SPECIAL HEALTH ISS

U.S.News & WORLD REPORT

DECEMBER 1, 2003

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# THE END OF HEART DISEASE

How new treatments are helping beat a killer

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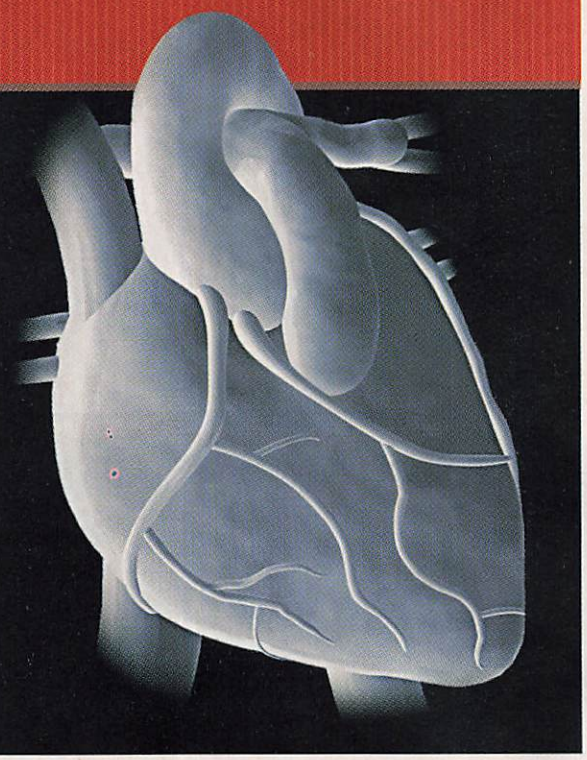
U.S.News & WORLD REPORT

DECEMBER 1, 2003 • VOLUME 135 • NUMBER 19

SPECIAL REPORT

# THE END OF HEART DISEASE



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# Washington Whispers

BY PAUL BEDARD

## From Wilson to Saddam: hide-and-seek advice

Think what you want about controversial diplomat **Joseph Wilson,** hubby of the CIA secret agent outed in revenge for his opposition to the Iraq war. But don't say that the last American official to shake **Saddam Hussein**'s hand doesn't know what he's talking about when it comes to the ex-dictator. Not that they were friends, but Wilson understands Saddam and has good insight into what the Iraqi would do to hide from U.S. troops. "If I were advising Saddam's security," says Wilson over breakfast, "it would be to put him in a rabidly [supportive] Sunni neighborhood in Baghdad where you have a lot of lookouts and you can move around the neighborhood more quickly than the Americans." Maybe grow a beard and stop using hair dye. "Let everything go white." And consider plastic surgery to your eyes and nose. Finally, shuck the uniform for one of those long robes. Good advice? Maybe, but Wilson says Uncle Sam hasn't asked his opinion. Explains a senior U.S. official, "Joe Wilson is the last guy I would go to for advice on how someone would maintain a low profile."

### CRAZY ECONOMICS

Give the White House some good economic news, and insiders go wacky. The latest: They predict labor *shortages* within three years.

### ISABEL ELBOW

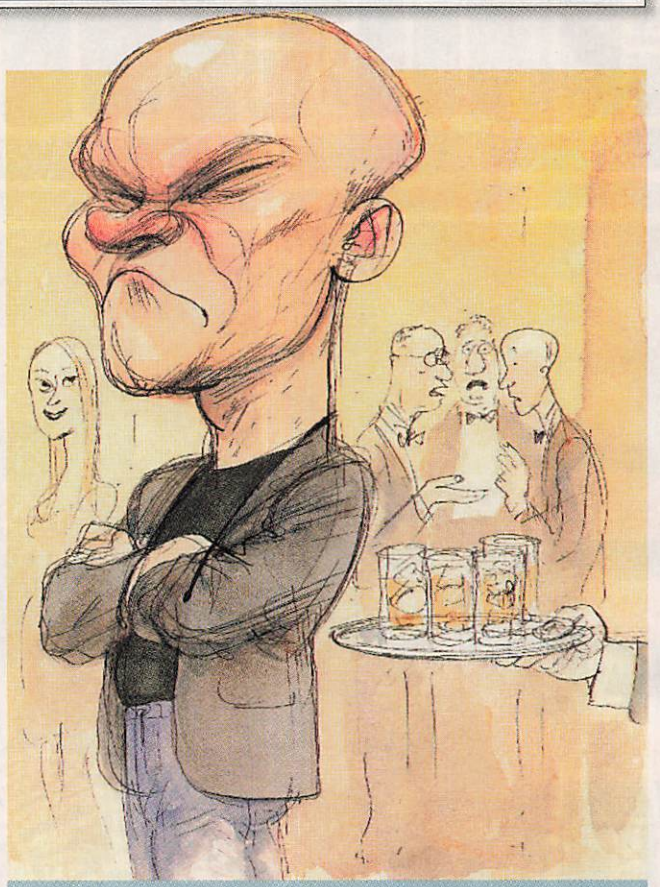
Former White House spokesman **Marlin Fitzwater** learned the value of community during the recent Hurricane Isabel, when the Chesapeake Bay storm surge wiped out his backyard dock, those of his neighbors, and even the Deale, Md., town pier. "All the boards popped off," he says. But instead of rushing to Home Depot, Fitzwater and his neighbors waded out to retrieve 90 percent of the AWOL planks. "I only had to buy four," he says. That means he found 36 boards. But nailing them back in place wasn't as easy. "I ended up," says Fitzwater, "with hammer elbow."

### FIGHTING FOR NO. 3

The upcoming Iowa caucus is turning into a donnybrook for the No. 3 spot. No. 1 and No. 2 seem reserved for Rep. **Dick Gephardt** and **Howard Dean.** A third-place finish is now considered key to fighting in New Hampshire and beyond. Thus, Sens. **John Kerry** and **John Edwards** are battling it out, with Kerry fans worried that a loss kills his chance to compete with Dean in the Granite State.

### FATHER TONY SNOW

The subject was humility and boldness last week when Fox News biggie **Tony Snow** led the White House Bible study group. Reviewing his talk with Whispers, Snow says humility is tough in a place "as heady as the White House." But keeping your cool while being bold in the heat of a campaign like **President Bush**'s re-



### THE JAMES CARVILLE 180-DAY RULE

Nobody loves the political chatter, sexy women, and free Maker's Mark at Washington cocktail parties more than **James Carville.** "I love to go to 'em," the inimitable Democratic consultant says. "They're fun. I like to drink too much." But he warns Democratic candidates to avoid them in the months leading up to Election Day. "It's just 180 days." The reason: "Democrats," he says, "get paralyzed by cocktail opinion." It's where, he barks, Democrats just sit around and complain about their plight and start cannibalizing one another. In his upcoming Bush-bashing, Democrats-fight-back book, *Had Enough?*, Carville does the unthinkable in self-important Washington. He includes a map of the cocktail party neighborhoods to avoid—Foxhall, Georgetown, Alexandria, Chevy Chase. He even tells us that GOP House Majority Leader **Tom DeLay** is a role model because he ducks parties. And if you go, he demands of Dems, "drink the whiskey, eat the food, flirt with the women, but don't take that chatter as strategy." His counsel: "Quit bitching and go to work. Be *for* something. That's the message."



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It's swim or swim.

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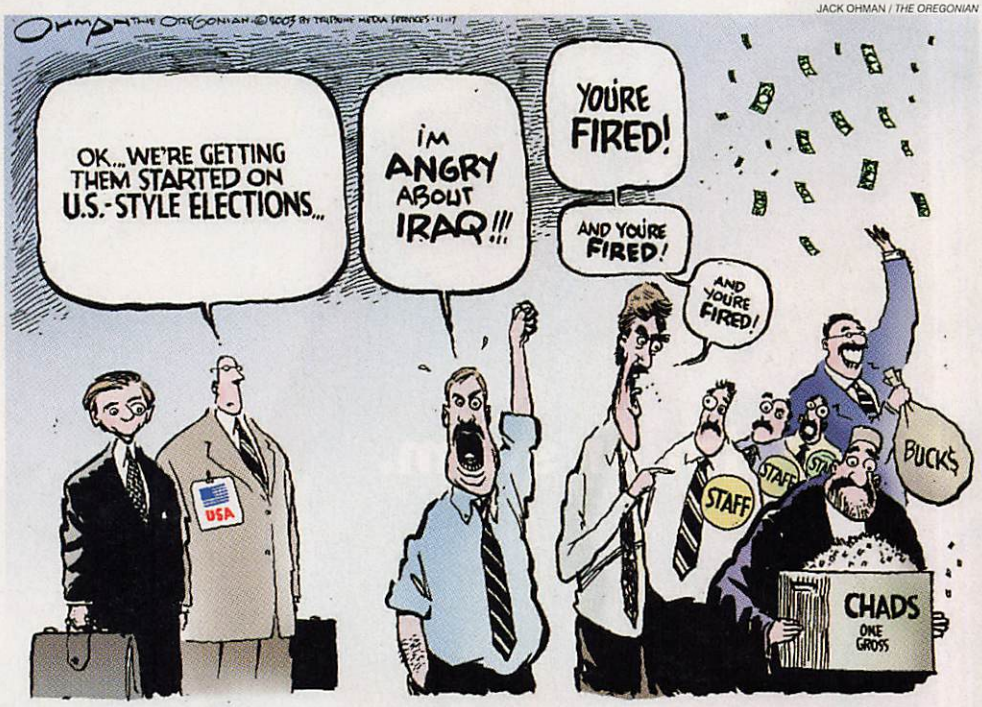


election bid is harder still. "There's such a tendency," he says, "to make everything personal, to turn everything into a vicious war where you have to destroy the other person." But, he counsels, "that kind of savagery is not consistent with your faith."

## VERMONT TEDDY BEAR

Democratic candidate **Howard Dean**'s angry-white-guy shtick turns out to be just an act, say those who know the hot presidential hopeful. "He's actually quite nice, considerate, and patient," says one. But, they add, Dean's keeping his in-your-face stance for now because it's working in the primaries. Should he get the nomination, "watch him show that teddy bear side."

## THE INTEL DUMP

Even as attacks on American forces in Iraq intensify, U.S. intelligence still does not have a clear picture of the structure of the guerrillas or their leadership. One reason: There's no center where military units can share what they have learned in the field. But we're told that might be fixed soon because the CIA is helping the Pentagon set up an intel center.

## THE WINNER'S ROOM

Whoever gets the Democratic presidential nod won't have to shop for campaign HQ space in Washington. That's because the new Democratic National Committee will have a first-ever "nominee's room," complete with computers, phones, and staff space.

## 'THANKSVEGAN'

Pardoned White House Thanksgiving turkeys rarely live long—last year's died of stress within nine months. So People for the Ethical Treatment of Animals wants **President Bush** to stop the happy talk about pardoning the birds and just go vegan this year. In fact, maybe the prez should adopt a bird, instead of pardoning one, says PETA's **Bruce Friedrich**. "Turkeys," he says in a letter to Bush being delivered this week, "are not as familiar to most of us as kittens and puppies, but they are interesting individuals."

## IT'S 'MRS. WILSON'

Back to our breakfast with former Ambassador **Joe Wilson**. About his outed CIA wife, **Valerie Plame,** he is asked how her name is pronounced. "Her last name is pronounced 'Wilson.' " Huh? "Plame is her maiden name. It's not a name she uses." Wow. What a mistake by the media. Still, neither Wilson is angry. That's because it has helped Valerie's efforts to build a family tree, a job made difficult when her granddad was "excommunicated" for marrying a non-Jew, says Wilson. "The fact that she was outed in her maiden name," he says, "has brought relatives who we didn't even know we had back into contact with us."

*With Kevin Whitelaw*

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## In Quotes

**"I don't want to live in Washington and sit in a room with a bunch of jerks I don't know."**
DENNIS MILLER, *the comic, on why he won't run for the Senate*

**"I want to shake them and say, 'C'mon, just *like* me.' "**
MONICA LEWINSKY, *saying her White House affair ruined dating*

**"Stop this God bless America stuff."**
MICHAEL MOORE, *the movie director, in Germany, criticizing the U.S.-led war in Iraq*

**"I want this guy out of here."**
MICHAEL DUKAKIS, *the 1988 Democratic loser, blasting President Bush*

**"The money was for travel, for food, for gratuities."**
RUSH LIMBAUGH, *rejecting money laundering allegations related to the probe of his drug use*

Sources: *Philadelphia Inquirer, GQ, Wall Street Journal, Portsmouth Herald, New York Daily News*

## WEB OF DECEIT

"CHINA DOLL" [ NOVEMBER 10] EXhibits an all-too-familiar feature common to the series of tales of FBI incompetence and failure to protect the national interest. There is a lack of accountability by any individual of authority. It ought to be clear that this organization is broken. It is time for Congress to craft legislation to strip this authority from the FBI and place it with a more capable agency. We simply cannot afford to be so ill-served in such dangerous times.

PLATT R. SAFFORD
*Kent, Ohio*

AMAZING! A COVER AND EIGHT PAGES on Katrina Leung but no description of her extensive connections with the Republican Party. She gave thousands to gubernatorial candidates Richard Riordan and Bill Simon in 2002. Rep. David Dreier appointed her a voting member of the party's state central committee. She was a supporter of the American Success Political Action Committee, which gave money to Republicans. She was seen dancing at one of the 2001 inaugural balls. Did the money for her generous political contributions come from the FBI or from her handlers in China? Should the Republicans give back the money?

GERT DESJARDIN
*Gainesville, Fla.*

WHILE I WAS IMpressed with the thorough coverage of the Katrina Leung FBI scandal, I was outraged to see "China Doll" as the chosen title of your article. As an Asian-American woman, I have battled my entire life to dispel the historical sexual objectification of Asian women. Leung stands accused of acting as a triple agent and betraying some of our country's most confidential and sensitive intelligence secrets. She may have jeopardized the lives of countless U.S. agents and officers. Leung was no doll but rather the puppeteer pulling the strings of some of our top FBI agents.

ROSALYNN W. HSU
*New York*

HOW THE MUTUAL FUND SCANDAL HURTS YOU
U.S.News & WORLD REPORT
EXCLUSIVE
TRIPLE CROSS
1 ACCUSED CHINESE SPY WHO SEDUCED 2 TOP FBI AGENTS. DID SHE WORK FOR 3 MASTERS?

U.S. NEWS IS RIGHT ON the ball again with telling it like it is in "China Doll." Why is Katrina Leung smiling when the article reports such terrible things? We remember when such betrayals quickly led to the gallows. Today there are book and movie offers. So many higher-ups have been implicated that accusations cancel each other out. Thus, the smile.

FRED W. BENEDICT
*Greenville, Ohio*

THE CHINA ESPIONAGE, THE MUTUALfund scandal ["Can You Trust Your Mutual Fund?" November 10], and the mergers ["Hold the Applause, Please," November 10] articles all seem to emphasize that the nation is for sale to the highest bidder. Like royalty, the participants demand privileges and take what they want from anyone. Is this American competition and democracy?

RICHARD NORLING
*Beverly Hills, Mich.*

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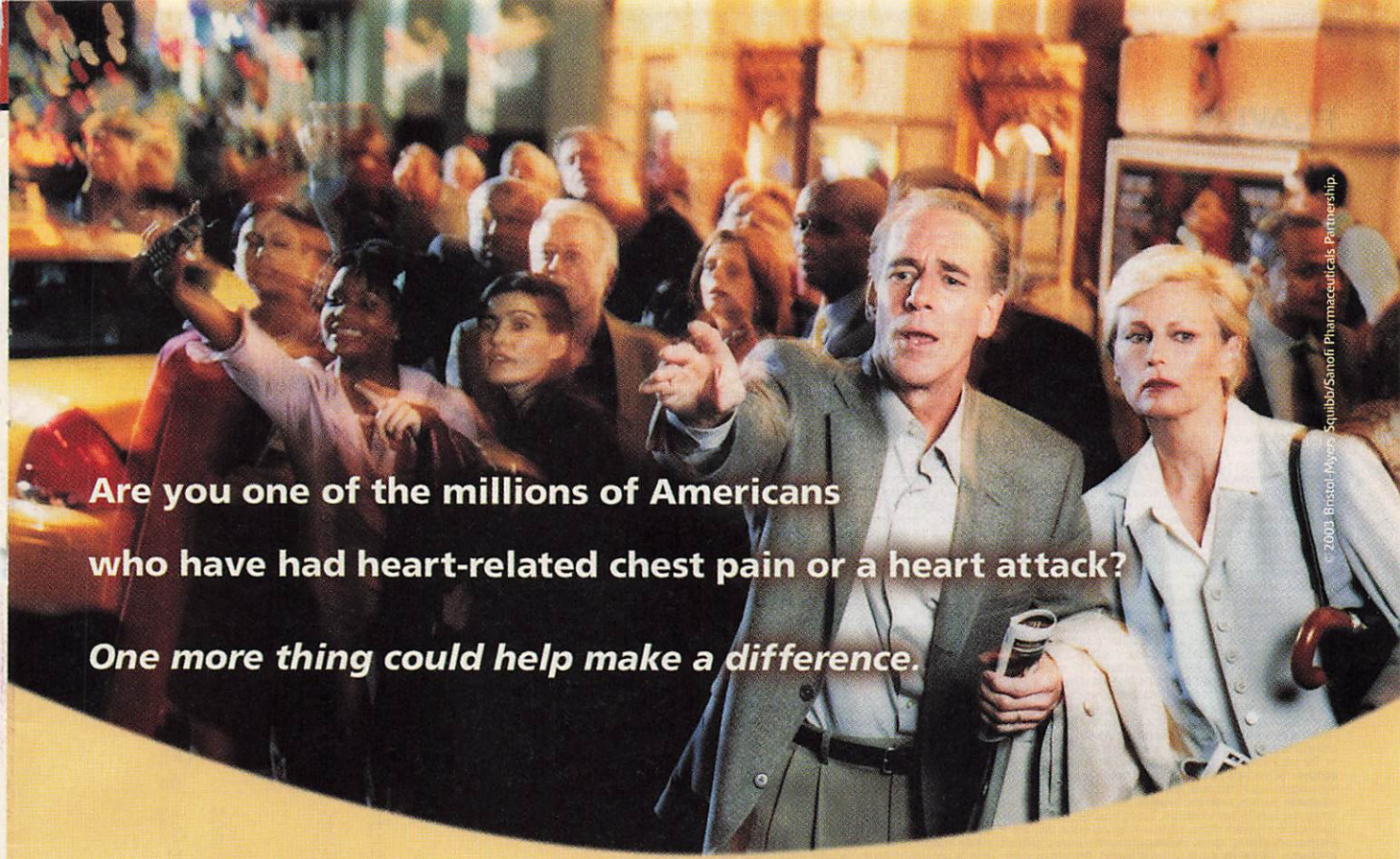
# The Week

BY LISA STEIN

JIM LO SCALZO FOR *USN&WR* (2)

## A PRESIDENT'S ROYAL FLUSH

LONDON—There was Queen Elizabeth II, looking suitably regal with a diamond tiara and, next to her, President Bush dressed to the nines in rented white tie and tails. Each rose to toast what Winston Churchill dubbed the "special relationship" between their two nations. It was a glamorous, picture-perfect evening. But the mood turned just hours later, after the twin terrorist bombings of British targets in Istanbul. The dead numbered 27, the injured more than 450 (story, Page 30). Envisioned as a symbol of post-9/11 solidarity when planning for the trip began 18 months ago, Bush's three-day visit—the first ever formal state visit by a U.S. president—came off instead as a bruising demonstration of post-Iraq war divisiveness. Some 100,000 antiwar, anti-Bush protesters packed Trafalgar Square, where they toppled a Saddam Hussein-like effigy of Bush. The president kept a British-style stiff upper lip as he joked that "the last noted American to visit London stayed in a glass box dangling over the Thames," referring to a much-derided, 44-day starvation stunt by U.S. street magician David Blaine. "A few might have been happy to provide similar arrangements for me." Fortunately, the queen had other plans. She and other royals welcomed the Bushes to Buckingham Palace with all due pomp and circumstance. There was a booming 41-gun salute, the parading of the royal household guard on horseback, and that white-tie-and-tails state banquet. Noting the queen's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**PLAVIX and your other medications work in different ways.** Adding PLAVIX can go beyond your current treatment. Prescription PLAVIX, taken with aspirin, plays its own role in keeping platelets from sticking together and forming clots—which helps keep blood flowing.

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**IMPORTANT INFORMATION:** If you have a medical condition that causes bleeding, such as stomach ulcer, you shouldn't use PLAVIX. The risk of bleeding may increase with PLAVIX, and when you take PLAVIX with certain other medicines, including aspirin. Review your medicines with your doctor to minimize this risk. Additional rare, but serious, side effects could occur.

Please see important product information on the following page.

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- **Recent MI, Recent Stroke or Established Peripheral Arterial Disease**
  For patients with a history of recent myocardial infarction (MI), recent stroke, or established peripheral arterial disease, PLAVIX has been shown to reduce the rate of a combined endpoint of new ischemic stroke (fatal or not), new MI (fatal or not), and other vascular death.
- **Acute Coronary Syndrome**
  For patients with acute coronary syndrome (unstable angina/non-Q-wave MI) including patients who are to be managed medically and those who are to be managed with percutaneous coronary intervention (with or without stent) or CABG, PLAVIX has been shown to decrease the rate of a combined endpoint of cardiovascular death, MI, or stroke as well as the rate of a combined endpoint of cardiovascular death, MI, stroke, or refractory ischemia.

**CONTRAINDICATIONS:** The use of PLAVIX is contraindicated in patients with a hypersensitivity to the drug substance or any component of the product, and those with active pathological bleeding such as peptic ulcer or intracranial hemorrhage.

**WARNINGS:** *Thrombotic thrombocytopenic purpura (TTP):* TTP has been reported rarely following use of PLAVIX, sometimes after a short exposure (<2 weeks). TTP is a serious condition requiring prompt treatment. It is characterized by thrombocytopenia, microangiopathic hemolytic anemia (schistocytes [fragmented RBCs] seen on peripheral smear), neurological findings, renal dysfunction, and fever. TTP was not seen during clopidogrel's clinical trials, which included over 17,500 clopidogrel-treated patients. In world-wide postmarketing experience, however, TTP has been reported at a rate of about four cases per million patients exposed, or about 11 cases per million patient-years. The background rate is thought to be about four cases per million person-years.

**PRECAUTIONS: General:** As with other antiplatelet agents, PLAVIX prolongs the bleeding time and therefore should be used with caution in patients who may be at risk of increased bleeding from trauma, surgery, or other pathological conditions (particularly gastrointestinal and intraocular). If a patient is to undergo elective surgery and an antiplatelet effect is not desired, PLAVIX should be discontinued 5 days prior to surgery. Due to the risk of bleeding and undesirable hematological effects, blood cell count determination and/or other appropriate testing should be promptly considered, whenever such suspected clinical symptoms arise during the course of treatment (see ADVERSE REACTIONS). *GI Bleeding:* In CAPRIE, PLAVIX was associated with a rate of gastrointestinal bleeding of 2.0%, vs 2.7% on aspirin. In CURE, the incidence of major gastrointestinal bleeding was 1.3% vs 0.7% (PLAVIX + aspirin vs placebo + aspirin, respectively). PLAVIX should be used with caution in patients who have lesions with a propensity to bleed (such as ulcers). Drugs that might induce such lesions should be used with caution in patients taking PLAVIX. *Use In Hepatically Impaired Patients:* Experience is limited in patients with severe hepatic disease, who may have bleeding diatheses. PLAVIX should be used with caution in this population. *Use in Renally-Impaired Patients:* Experience is limited in patients with severe renal impairment. PLAVIX should be used with caution in this population.

**Information for Patients:** Patients should be told that it may take them longer than usual to stop bleeding when they take PLAVIX, and that they should report any unusual bleeding to their physician. Patients should inform physicians and dentists that they are taking PLAVIX before any surgery is scheduled and before any new drug is taken.

**Drug Interactions:** Study of specific drug interactions yielded the following results: *Aspirin:* Aspirin did not modify the clopidogrel-mediated inhibition of ADP-induced platelet aggregation. Concomitant administration of 500 mg of aspirin twice a day for 1 day did not significantly increase the prolongation of bleeding time induced by PLAVIX. PLAVIX potentiated the effect of aspirin on collagen-induced platelet aggregation. PLAVIX and aspirin have been administered together for up to one year. *Heparin:* In a study in healthy volunteers, PLAVIX did not necessitate modification of the heparin dose or alter the effect of heparin on coagulation. Coadministration of heparin had no effect on inhibition of platelet aggregation induced by PLAVIX. *Nonsteroidal Anti-Inflammatory Drugs (NSAIDs):* In healthy volunteers receiving naproxen, concomitant administration of PLAVIX was associated with increased occult gastrointestinal blood loss. NSAIDs and PLAVIX should be coadministered with caution. *Warfarin:* The safety of the coadministration of PLAVIX with warfarin has not been established. Consequently, concomitant administration of these two agents should be undertaken with caution. (See **Precautions–General.**) *Other Concomitant Therapy:* No clinically significant pharmacodynamic interactions were observed when PLAVIX was coadministered with **atenolol, nifedipine**, or both atenolol and nifedipine. The pharmacodynamic activity of PLAVIX was also not significantly influenced by the coadministration of **phenobarbital, cimetidine** or **estrogen**. The pharmacokinetics of **digoxin** or **theophylline** were not modified by the coadministration of PLAVIX (clopidogrel bisulfate). At high concentrations *in vitro*, clopidogrel inhibits $P_{450}$ 2C9. Accordingly, PLAVIX may interfere with the metabolism of **phenytoin, tamoxifen, tolbutamide, warfarin, torsemide, fluvastatin**, and many **non-steroidal anti-inflammatory agents**, but there are no data with which to predict the magnitude of these interactions. Caution should be used when any of these drugs is coadministered with PLAVIX. In addition to the above specific interaction studies, patients entered into clinical trials with PLAVIX received a variety of concomitant medications including **diuretics, beta-blocking agents, angiotensin converting enzyme inhibitors, calcium antagonists, cholesterol lowering agents, coronary vasodilators, antidiabetic agents (including insulin), antiepileptic agents, hormone replacement therapy, heparins** (unfractionated and LMWH), and GPIIb/IIIa **antagonists** without evidence of clinically significant adverse interactions. The use of oral anticoagulants, non-study anti-platelet drug and chronic NSAIDs was not allowed in CURE and there are no data on their concomitant use with clopidogrel.

**Drug/Laboratory Test Interactions:** None known.

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** There was no evidence of tumorigenicity when clopidogrel was administered for 78 weeks to mice and 104 weeks to rats at dosages up to 77 mg/kg per day, which afforded plasma exposures >25 times that in humans at the recommended daily dose of 75 mg. Clopidogrel was not genotoxic in four *in vitro* tests (Ames test, DNA-repair test in rat hepatocytes, gene mutation assay in Chinese hamster fibroblasts, and metaphase chromosome analysis of human lymphocytes) and in one *in vivo* test (micronucleus test by oral route in mice). Clopidogrel was found to have no effect on fertility of male and female rats at oral doses up to 400 mg/kg per day (52 times the recommended human dose on a mg/m² basis).

**Pregnancy:** Pregnancy Category B. Reproduction studies performed in rats and rabbits at doses up to 500 and 300 mg/kg/day (respectively, 65 and 78 times the recommended daily human dose on a mg/m² basis), revealed no evidence of impaired fertility or fetotoxicity due to clopidogrel. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of a human response, PLAVIX should be used during pregnancy only if clearly needed.

**Nursing Mothers:** Studies in rats have shown that clopidogrel and/or its metabolites are excreted in the milk. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the nursing woman.

**Pediatric Use:** Safety and effectiveness in the pediatric population have not been established.

**ADVERSE REACTIONS:** PLAVIX has been evaluated for safety in more than 17,500 patients, including over 9,000 patients treated for 1 year or more. The overall tolerability of PLAVIX in CAPRIE was similar to that of aspirin regardless of age, gender and race, with an approximately equal incidence (13%) of patients withdrawing from treatment because of adverse reactions. The clinically important adverse events observed in CAPRIE and CURE are discussed below.

*Hemorrhagic:* In CAPRIE patients receiving PLAVIX, gastrointestinal hemorrhage occurred at a rate of 2.0%, and required hospitalization in 0.7%. In patients receiving aspirin, the corresponding rates were 2.7% and 1.1%, respectively. The incidence of intracranial hemorrhage was 0.4% for PLAVIX compared to 0.5% for aspirin.

In CURE, PLAVIX use with aspirin was associated with an increase in bleeding compared to placebo with aspirin (see Table 3). There was an excess in major bleeding in patients receiving PLAVIX plus aspirin compared with placebo plus aspirin, primarily gastrointestinal and at puncture sites. The incidence of intracranial hemorrhage (0.1%), and fatal bleeding (0.2%), was the same in both groups.

In patients receiving both PLAVIX and aspirin in CURE, the incidence of bleeding is described below.

**CURE Incidence of bleeding complications (% patients)**

| Event | PLAVIX (+ aspirin)* (n=6259) | Placebo (+ aspirin)* (n=6303) | P-value |
|---|---|---|---|
| Major bleeding† | 3.7‡ | 2.7§ | 0.001 |
| Life-threatening bleeding | 2.2 | 1.8 | 0.13 |
| Fatal | 0.2 | 0.2 | |
| 5 g/dL hemoglobin drop | 0.9 | 0.9 | |
| Requiring surgical intervention | 0.7 | 0.7 | |
| Hemorrhagic strokes | 0.1 | 0.1 | |
| Requiring inotropes | 0.5 | 0.5 | |
| Requiring transfusion (≥4 units) | 1.2 | 1.0 | |
| Other major bleeding | 1.6 | 1.0 | 0.005 |
| Significantly disabling | 0.4 | 0.3 | |
| Intraocular bleeding with significant loss of vision | 0.05 | 0.03 | |
| Requiring 2-3 units of blood | 1.3 | 0.9 | |
| Minor bleeding¶ | 5.1 | 2.4 | <0.001 |

* Other standard therapies were used as appropriate.
† Life threatening and other major bleeding.
‡ Major bleeding event rate for PLAVIX + aspirin was dose-dependent on aspirin: <100 mg=2.6%; 100-200 mg=3.5%; >200 mg=4.9%
§ Major bleeding event rate for placebo + aspirin was dose-dependent on aspirin: <100 mg=2.0%; 100-200 mg=2.3%; >200 mg=4.0%
¶ Led to interruption of study medication.

Ninety-two percent (92%) of the patients in the CURE study received heparin/LMWH, and the rate of bleeding in these patients was similar to the overall results.

There was no excess in major bleeds within seven days after coronary bypass graft surgery in patients who stopped therapy more than five days prior to surgery (event rate 4.4% PLAVIX + aspirin; 5.3% placebo + aspirin). In patients who remained on therapy within five days of bypass graft surgery, the event rate was 9.6% for PLAVIX + aspirin, and 6.3% for placebo + aspirin.

*Neutropenia/agranulocytosis:* Ticlopidine, a drug chemically similar to PLAVIX, is associated with a 0.8% rate of severe neutropenia (less than 450 neutrophils/μL). In CAPRIE severe neutropenia was observed in six patients, four on PLAVIX and two on aspirin. Two of the 9599 patients who received PLAVIX and none of the 9586 patients who received aspirin had neutrophil counts of zero. One of the four PLAVIX patients in CAPRIE was receiving cytotoxic chemotherapy, and another recovered and returned to the trial after only temporarily interrupting treatment with PLAVIX (clopidogrel bisulfate). In CURE, the numbers of patients with thrombocytopenia (19 PLAVIX + aspirin vs 24 placebo + aspirin) or neutropenia (3 vs 3) were similar.

Although the risk of myelotoxicity with PLAVIX thus appears to be quite low, this possibility should be considered when a patient receiving PLAVIX demonstrates fever or other sign of infection.

*Gastrointestinal:* Overall, the incidence of gastrointestinal events (e.g. abdominal pain, dyspepsia, gastritis and constipation) in patients receiving PLAVIX (clopidogrel bisulfate) was 27.1%, compared to 29.8% in those receiving aspirin in the CAPRIE trial. In the CURE trial the incidence of these gastrointestinal events for patients receiving PLAVIX + aspirin was 11.7% compared to 12.5% for those receiving placebo + aspirin.

In the CAPRIE trial, the incidence of peptic, gastric or duodenal ulcers was 0.7% for PLAVIX and 1.2% for aspirin. In the CURE trial the incidence of peptic, gastric or duodenal ulcers was 0.4% for PLAVIX + aspirin and 0.3% for placebo + aspirin.

Cases of diarrhea were reported in the CAPRIE trial in 4.5% of patients in the PLAVIX group compared to 3.4% in the aspirin group. However, these were rarely severe (PLAVIX=0.2% and aspirin=0.1%). In the CURE trial, the incidence of diarrhea for patients receiving PLAVIX + aspirin was 2.1% compared to 2.2% for those receiving placebo + aspirin.

In the CAPRIE trial, the incidence of patients withdrawing from treatment because of gastrointestinal adverse reactions was 3.2% for PLAVIX and 4.0% for aspirin. In the CURE trial, the incidence of patients withdrawing from treatment because of gastrointestinal adverse reactions was 0.9% for PLAVIX + aspirin compared with 0.8% for placebo + aspirin.

*Rash and Other Skin Disorders:* In the CAPRIE trial, the incidence of skin and appendage disorders in patients receiving PLAVIX was 15.8% (0.7% serious); the corresponding rate in aspirin patients was 13.1% (0.5% serious). In the CURE trial the incidence of rash or other skin disorders in patients receiving PLAVIX + aspirin was 4.0% compared to 3.5% for those receiving placebo + aspirin.

In the CAPRIE trial, the overall incidence of patients withdrawing from treatment because of skin and appendage disorders adverse reactions was 1.5% for PLAVIX and 0.8% for aspirin. In the CURE trial, the incidence of patients withdrawing because of skin and appendage disorders adverse reactions was 0.7% for PLAVIX + aspirin compared with 0.3% for placebo + aspirin.

Adverse events occurring in ≥2.5% of patients on PLAVIX in the CAPRIE controlled clinical trial are shown below regardless of relationship to PLAVIX. The median duration of therapy was 20 months, with a maximum of 3 years.

**Adverse Events Occurring in ≥2.5% of PLAVIX Patients in CAPRIE**

| Body System / Event | % Incidence (% Discontinuation) PLAVIX (n=9599) | | Aspirin (n=9586) | |
|---|---|---|---|---|
| *Body as a Whole — general disorders* | | | | |
| Chest Pain | 8.3 | (0.2) | 8.3 | (0.3) |
| Accidental/Inflicted Injury | 7.9 | (0.1) | 7.3 | (0.1) |
| Influenza-like symptoms | 7.5 | (<0.1) | 7.0 | (<0.1) |
| Pain | 6.4 | (0.1) | 6.3 | (0.1) |
| Fatigue | 3.3 | (0.1) | 3.4 | (0.1) |
| *Cardiovascular disorders, general* | | | | |
| Edema | 4.1 | (<0.1) | 4.5 | (<0.1) |
| Hypertension | 4.3 | (<0.1) | 5.1 | (<0.1) |
| *Central & peripheral nervous system disorders* | | | | |
| Headache | 7.6 | (0.3) | 7.2 | (0.2) |
| Dizziness | 6.2 | (0.2) | 6.7 | (0.3) |
| *Gastrointestinal system disorders* | | | | |
| Abdominal pain | 5.6 | (0.7) | 7.1 | (1.0) |
| Dyspepsia | 5.2 | (0.6) | 6.1 | (0.7) |
| Diarrhea | 4.5 | (0.4) | 3.4 | (0.3) |
| Nausea | 3.4 | (0.5) | 3.8 | (0.4) |
| *Metabolic & nutritional disorders* | | | | |
| Hypercholesterolemia | 4.0 | (0) | 4.4 | (<0.1) |
| *Musculo-skeletal system disorders* | | | | |
| Arthralgia | 6.3 | (0.1) | 6.2 | (0.1) |
| Back Pain | 5.8 | (0.1) | 5.3 | (<0.1) |
| *Platelet, bleeding, & clotting disorders* | | | | |
| Purpura/Bruise | 5.3 | (0.3) | 3.7 | (0.1) |
| Epistaxis | 2.9 | (0.2) | 2.5 | (0.1) |
| *Psychiatric disorders* | | | | |
| Depression | 3.6 | (0.1) | 3.9 | (0.2) |
| *Respiratory system disorders* | | | | |
| Upper resp tract infection | 8.7 | (<0.1) | 8.3 | (<0.1) |
| Dyspnea | 4.5 | (0.1) | 4.7 | (0.1) |
| Rhinitis | 4.2 | (0.1) | 4.2 | (<0.1) |
| Bronchitis | 3.7 | (0.1) | 3.7 | (0) |
| Coughing | 3.1 | (<0.1) | 2.7 | (<0.1) |
| *Skin & appendage disorders* | | | | |
| Rash | 4.2 | (0.5) | 3.5 | (0.2) |
| Pruritus | 3.3 | (0.3) | 1.6 | (0.1) |
| *Urinary system disorders* | | | | |
| Urinary tract infection | 3.1 | (0) | 3.5 | (0.1) |

Incidence of discontinuation, regardless of relationship to therapy, is shown in parentheses.

Adverse events occurring in ≥2.0% of patients on PLAVIX in the CURE controlled clinical trial are shown below regardless of relationship to PLAVIX.

**Adverse Events Occurring in ≥2.0% of PLAVIX Patients in CURE**

| Body System / Event | % Incidence (% Discontinuation) PLAVIX (+ aspirin)* (n=6259) | | Placebo (+ aspirin)* (n=6303) | |
|---|---|---|---|---|
| *Body as a Whole–general disorders* | | | | |
| Chest Pain | 2.7 | (<0.1) | 2.8 | (0.0) |
| *Central & peripheral nervous system disorders* | | | | |
| Headache | 3.1 | (0.1) | 3.2 | (0.1) |
| Dizziness | 2.4 | (0.1) | 2.0 | (<0.1) |
| *Gastrointestinal system disorders* | | | | |
| Abdominal pain | 2.3 | (0.3) | 2.8 | (0.3) |
| Dyspepsia | 2.0 | (0.1) | 1.9 | (<0.1) |
| Diarrhea | 2.1 | (0.1) | 2.2 | (0.1) |

* Other standard therapies were used as appropriate.

Other adverse experiences of potential importance occurring in 1% to 2.5% of patients receiving PLAVIX (clopidogrel bisulfate) in the CAPRIE or CURE controlled clinical trials are listed below regardless of relationship to PLAVIX. In general, the incidence of these events was similar to that in patients receiving aspirin (in CAPRIE) or placebo + aspirin (in CURE).

*Autonomic Nervous System Disorders:* Syncope, Palpitation. *Body as a Whole - general disorders:* Asthenia, Fever, Hernia. *Cardiovascular disorders:* Cardiac failure. *Central and peripheral nervous system disorders:* Cramps legs, Hypoaesthesia, Neuralgia, Paraesthesia, Vertigo. *Gastrointestinal system disorders:* Constipation, Vomiting. *Heart rate and rhythm disorders:* Fibrillation atrial. *Liver and biliary system disorders:* Hepatic enzymes increased. *Metabolic and nutritional disorders:* Gout, hyperuricemia, non-protein nitrogen (NPN) increased. *Musculo-skeletal system disorders:* Arthritis, Arthrosis. *Platelet, bleeding & clotting disorders:* GI hemorrhage, hematoma, platelets decreased. *Psychiatric disorders:* Anxiety, Insomnia. *Red blood cell disorders:* Anemia. *Respiratory system disorders:* Pneumonia, Sinusitis. *Skin and appendage disorders:* Eczema, Skin ulceration. *Urinary system disorders:* Cystitis. *Vision disorders:* Cataract, Conjunctivitis.

Other potentially serious adverse events which may be of clinical interest but were rarely reported (<1%) in patients who received PLAVIX in the CAPRIE or CURE controlled clinical trials are listed below regardless of relationship to PLAVIX. In general, the incidence of these events was similar to that in patients receiving aspirin (in CAPRIE) or placebo + aspirin (in CURE). *Body as a whole:* Allergic reaction, necrosis ischemic. *Cardiovascular disorders:* Edema generalized. *Gastrointestinal system disorders:* Gastric ulcer perforated, gastritis hemorrhagic, upper GI ulcer hemorrhagic. *Liver and Biliary system disorders:* Bilirubinemia, hepatitis infectious, liver fatty. *Platelet, bleeding and clotting disorders:* hemarthrosis, hematuria, hemoptysis, hemorrhage intracranial, hemorrhage retroperitoneal, hemorrhage of operative wound, ocular hemorrhage, pulmonary hemorrhage, purpura allergic, thrombocytopenia. *Red blood cell disorders:* Anemia aplastic, anemia hypochromic. *Reproductive disorders, female:* Menorrhagia. *Respiratory system disorders:* Hemothorax. *Skin and appendage disorders:* Bullous eruption, rash erythematous, rash maculopapular, urticaria. *Urinary system disorders:* Abnormal renal function, acute renal failure. *White cell and reticuloendothelial system disorders:* Agranulocytosis, granulocytopenia, leukemia, leukopenia, neutrophils decreased.

**Postmarketing Experience:** The following events have been reported spontaneously from worldwide postmarketing experience: *Body as a whole:* hypersensitivity reactions, anaphylactoid reactions. *Central and Peripheral Nervous System disorders:* confusion, hallucinations, taste disorders. *Liver and Biliary system disorders:* abnormal liver function test, hepatitis (non-infectious). *Platelet, Bleeding and Clotting disorders:* cases of bleeding with fatal outcome (especially intracranial, gastrointestinal and retroperitoneal hemorrhage), agranulocytosis, aplastic anemia/pancytopenia, thrombotic thrombocytopenic purpura (TTP) – see WARNINGS, conjunctival, ocular and retinal bleeding. *Respiratory system disorders:* bronchospasm *Skin and Appendage disorders:* angioedema, erythema multiforme *Urinary system disorders:* glomerulopathy, abnormal creatinine levels

**OVERDOSAGE:** One case of deliberate overdosage with PLAVIX was reported in the large, CAPRIE controlled clinical study. A 34-year-old woman took a single 1,050-mg dose of PLAVIX (equivalent to 14 standard 75-mg tablets). There were no associated adverse events. No special therapy was instituted, and she recovered without sequelae. No adverse events were reported after single oral administration of 600 mg (equivalent to 8 standard 75-mg tablets) of PLAVIX in healthy volunteers. The bleeding time was prolonged by a factor of 1.7, which is similar to that typically observed with the therapeutic dose of 75 mg of PLAVIX per day. A single oral dose of clopidogrel at 1500 or 2000 mg/kg was lethal to mice and to rats and at 3000 mg/kg to baboons. Symptoms of acute toxicity were vomiting (in baboons), prostration, difficult breathing, and gastrointestinal hemorrhage in all species.

**Recommendations About Specific Treatment:** Based on biological plausibility, platelet transfusion may be appropriate to reverse the pharmacological effects of PLAVIX if quick reversal is required.

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hospitality, the president said he was honored to be staying at "her house," referring to the 600-room palace that has been the official residence of British monarchs since 1837. The queen, though, was reportedly miffed at the Americans' elaborate security precautions, including a request for blast-resistant windows in the president's suite (which she nixed). Extraordinary security measures put 5,123 London Metropolitan Police officers on duty—at a cost of $9 million. That's $3.60 per local taxpayer, grumbled London's leftist Mayor Ken Livingstone, who sniffed that the locals would gladly have paid twice that amount for the president to have stayed away. And if authorities weren't already edgy enough, the tabloid *Daily Mirror* reported the "biggest royal security scandal ever," offering a 15-page account of how undercover reporter Ryan Parry got hired as a Buckingham Palace footman despite "bogus" references. During his two months at the palace, his tasks included delivering food to the queen (who, we learn, feeds toast with marmalade to her corgis at breakfast while husband Prince Philip reads the *Racing Post*). "Had I been a terrorist intent on assassinating the queen or President George Bush," Parry wrote, "I could have done so with absolute ease." That account couldn't have pleased the queen, particularly in the wake of a whispering campaign about an alleged (and denied) "sexual incident" involving Prince Charles and a royal household employee.

● *Brushing off the protests, Bush vowed to stay the course in Iraq and to press for the spread of democracy in the region. And whatever their views of Bush or the Iraq war, a poll by the* Guardian *newspaper found that two thirds of British voters favor keeping troops in Iraq until the situation is more stable. –Terry Atlas*

ROBYN BECK—AFP / GETTY IMAGES

**BOOKED. The "Gloved One" became the cuffed one briefly after he was arrested and charged with child molesting last week. Michael Jackson, 45, gestures after being released on $3 million bail. The entertainer's lawyer, Mark Geragos (left), called the charges "a big lie."**

COURTS

## TIES THAT BIND

The Massachusetts Supreme Judicial Court last week ruled that same-sex couples have a constitutional right to civil marriages, declaring that "the right to marry means little if it does not include the right to marry the person of one's choice." Gay advocates hailed the 4-to-3 decision, but it was immediately denounced by a parade of conservative pols. Among them: President Bush, who pledged to take whatever steps "legally necessary to defend the sanctity of marriage," which he described as "a sacred institution between a man and a woman." The court delayed the decision for 180 days to give the legislature time to respond.

● *"This ruling allows everyone to partake of the same benefits and privileges that our society extends to married couples," says Sam Thoron of Parents, Families, and Friends of Lesbians and Gays. "We call upon the . . . legislature to do the right thing . . . and extend full marriage rights to same-sex couples."*

## A SNIPER VERDICT

After deliberating for nearly seven hours, a jury last week found John Allen Muhammad, 42, guilty of capital murder in the death of engineer Dean Harold Meyers, 53, gunned down while pumping gas in Northern Virginia last fall. During the monthlong trial, prosecutors had argued that Muhammad directed a 23-day shooting spree in October 2002 aimed at extorting $10 million from the government by terrorizing the Washington, D.C., area and killing 10 people. In the separate trial of Muhammad's alleged accomplice, Lee Boyd Malvo, 18, prosecutors last week played a tape of a Nov. 7, 2002, police interview of Malvo after his arrest. On the tape, an officer asks Malvo if he had hoped some of his victims might survive; replies the teen: "I intended to kill them all."

● *Prosecutors are seeking the death penalty for Muhammad.*

John Allen Muhammad

ADRIN SNIDER—AFP / GETTY IMAGES / POOL

BUSINESS

## TRADE BRAHAHA

Who knew? The White House says bras made in China are a danger to America—and must be limited. The reason: China is flooding the United States with cheap underthings, taking away business from domestic manufacturers. To stem the purported damage, the administration announced new quotas last week limiting imports of lingerie, robes, and other textiles

from China. As you can imagine, China was none too pleased; ditto Fed Chairman Alan Greenspan. "It is imperative," he said, "that creeping protectionism be thwarted and reversed."
● *The quotas also spooked currency traders, who pushed the dollar to new lows against the euro.*

## TIME THIS

For the first time, top execs of a fund firm have been charged with wrongdoing in the growing mutual fund scandal. Last week, the New York attorney general's office and the Securities Exchange Commission filed civil charges against Gary Pilgrim, 63, a PBHG founder, for allegedly profiting from a hedge fund that was allowed to rapidly trade shares of PBHG funds. This practice, known as market timing, hurts long-term shareholders and is at the center of the scandal. Civil charges were also filed against cofounder Harold Baxter, 57, for allegedly giving "nonpublic" information about PBHG holdings to a pal in the brokerage business, who passed it to clients who used it to market-time PBHG fund shares.
● *Pilgrim and Baxter recently resigned their posts.*

CONGRESS

## GUN CONTROL

Democratic Rep. Tom Lantos of California last week introduced a bill to ban U.S. companies from exporting stun guns and similar devices to nations cited by the State Department for torturing dissidents. The move came just days after *U.S. News* revealed that in 2001 and 2002 the United States permitted American companies to ship electroshock weapons and mechanical restraints to 39 nations where authorities are accused of torturing prisoners.
● *"This legislation," says Lantos, a Holocaust survivor, "aims to prevent people from being tortured."*

GARY FABIANO—SIPA

**MIAMI HEAT.** Police clash with hundreds of demonstrators protesting trade talks in Miami last week to create a Free Trade Area of the Americas. Critics say the proposed free-trade zone will send thousands of jobs abroad and hurt the environment; there were some 140 arrests.

STAN HONDA—AFP / GETTY IMAGES

**BEND IT LIKE BECKHAM.** Soccer phenom Freddy Adu, 14, of Ghana and now Maryland, cut a deal with Major League Soccer to play for D.C. United.

HEALTH

## OOPS!

You know that shot you got that was supposed to protect you from the latest flu epidemic this winter? Bad news: It didn't contain the right vaccine mix. What does *that* mean? In a nutshell: Health agencies guessed wrong about the flu strains circulating this year—and when whipping up the vaccination failed to include the Fujian, which turns out to be a dominant strain. The Centers for Disease Control and Prevention says the inoculated may still be OK, because the injection included a genetically close relative to Fujian, called Panama—probably providing some protection.
● *CDC's advice: You should still get the shot, or else you'll be totally vulnerable to the Fujian flu. And what about the other strains experts may have missed? Pass the chicken soup—and check* CDC.gov.

SCIENCE

## A WHALE OF A TALE

Japanese scientists last week identified a new species of baleen whale (the big guys with the funny stuff in their mouths for straining water) living in the Pacific. You'd think someone would have noticed before now, but to the casual observer—a harpooner on a whaling ship, say—*Balaenoptera omurai* looks an awful lot like other whales. Specialists say they aren't terribly surprised by the finding, reported in *Nature,* and question the value of Japan's "scientific whaling" program, which critics charge amounts to little more than weighing the animals *before* cutting them into steaks. University of Auckland geneticist Scott Baker says there's no need to kill whales to study them, as Japan's scientists do. "There's very little that can't be done by nonlethal methods today," he says.
● *Genetic analysis may reveal still more whale species, he says—a student of his found one last year—but because of hunting, noise pollution, and other run-ins with humans, "some may be disappearing while we're trying to find them."*

Sprint

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# ANATOMY OF A DEBATE

## Why the candidates hate what TV loves, and vice versa

BY ROGER SIMON

Tom Brokaw enters the 14th-floor conference room at 30 Rockefeller Plaza through a side door. He is wearing a zippered black sweater and carrying a cardboard cup of soup. He has glasses on. The 16 people seated around the table, the half dozen more seated along the walls, and the five people connected to the meeting via a conference call fall silent. The meeting has been convened to plan this week's debate among the Democratic presidential candidates in Des Moines, which NBC News and MSNBC will produce. An 18-point agenda for the meeting has been distributed, and it includes everything from "Candidates—movements, handling" to "Press room/Spin Alley." It is like planning a small war. Or a live TV show.

Though "Brokaw speaks" is not on the agenda, everyone expects him to. He is the anchor and managing editor of NBC's *Nightly News,* a bestselling author, and the winner of numerous awards. The first presidential election he covered was in 1968. This will be his last. He is 63 and will retire from the *Nightly News* at the end of the 2004 presidential campaign. This fact tends to heighten the events he participates in. He



PHOTOGRAPHY BY CHARLIE ARCHAMBAULT FOR *USN&WR*

**PREP WORK.** NBC personnel talk with Democratic operatives at the Polk County Convention Complex (left). Below, Tom Brokaw gestures during a production meeting in New York.

will moderate and be the sole questioner of the candidates in Des Moines. Though some of the rules and format of the debate have been negotiated among NBC, the Democratic National Committee, and the presidential campaigns, Brokaw intends to do pretty much what he wants to do. And he has set an extremely high goal for himself and the 100 or so NBC employees who are actively working on the event. "I want," Brokaw tells the group, "to try to make it memorable."

Glances are exchanged. "Informative" would be hard enough. "Watchable" may even be a challenge. But "memorable"? Four debates officially sanctioned by the DNC have already taken place this year, as well as dozens more unsanctioned debates and forums. A few have been interesting, and one or two briefly made some news. But memorable is going to be one tough hill to climb. Brokaw intends to go for it, however. And the first way he intends to achieve memorability is to knock the candidates off balance. "Because the [candidates] will come to this with their eyes semiglazed over because they've been to so many of these," Brokaw says, "we have to get off to a very fast start."

**Reaction time.** He does not want the debate to be about the "fine print" of the campaigns, he explains. He does not want it to be about "the healthcare niche of [Richard] Gephardt or the John Kerry Vietnam veteran niche" but rather about the candidates' "character and their values, and their vision and their feelings about each other." His big goal, Brokaw says, is that at the end of two hours the audience will have a much better sense of the "whole person" and "what drives them as human beings as much as presidential candidates." Which is easier said than done, but Brokaw realizes that. "I am still working through my own mind about the questions," Brokaw says, "and how to orchestrate this on stage." One of his strategies is going to be to interrupt the candidates to ask "a counterintuitive question" in the middle of any long, scripted answer. "If they get into a big anti-Bush economy screed, I may interrupt that with another kind of a question," Brokaw says. "We will try to get at them and make them think on their feet. I want the viewers to see how these guys react."

In other words, the candidates will probably hate this debate. Some months ago, the candidates asked the Democratic National Committee to step in and impose some order on the debate process for two reasons: First, they were getting too many invitations and wanted the DNC to sanction just six debates. This would give the candidates an excuse to turn down other offers. (As it turned out, it gave them an excuse, but not the guts. The candidates found it impossible to refuse the unsanctioned invitations of such groups as the National Association for the Advancement of Colored People.) Second, before the sanctioning process was set up, ABC held a debate in Columbia, S.C.,

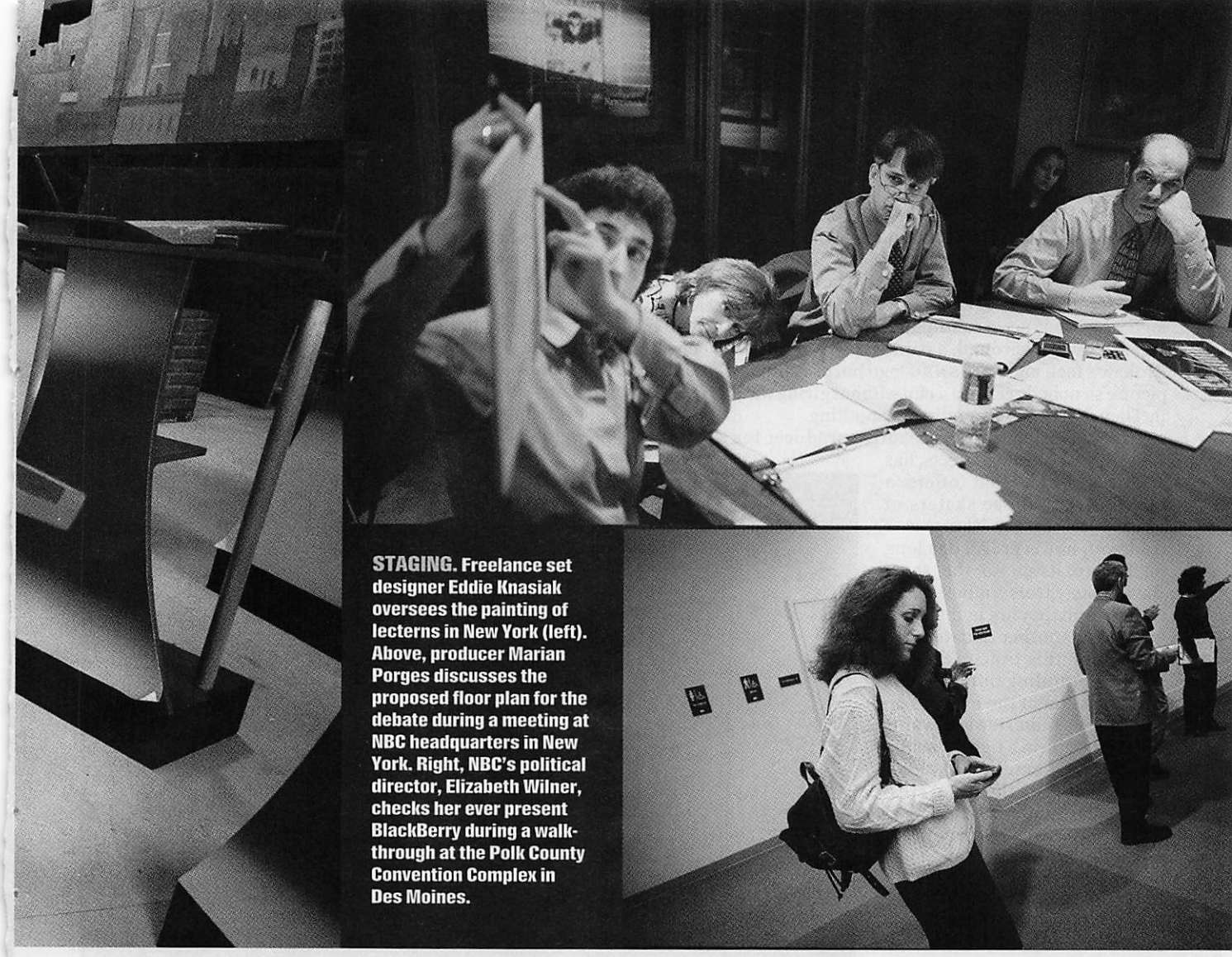
moderated by George Stephanopoulos. It received good reviews from journalists but was loathed by the candidates. ABC made the candidates sit at desks on the stage while Stephanopoulos strode around in front of them asking questions. "They hated George standing over them," a Democratic strategist familiar with the debate negotiations said. "They hated sitting at those desks. They hated that the debate seemed to be focused more on George than on them."

So the DNC stepped in and began discussions with the networks for carrying sanctioned debates. (CBS dropped out of the process early on, and the DNC would not sit down with Fox, because, in the words of one DNC official, "Fox is unfair, unbalanced, and spends 24 hours a day attacking Democrats.") But before the networks could get a debate, they had to outline the formats that they wanted to use and that the DNC, on behalf of the candidates, could negotiate. "The first thing the candidates wanted was no more little damn desks," one consultant said. (In Iowa, NBC will use lecterns and tall stools.) The complaints did not stop with the furniture, however. After a CNN debate, many of the candidates were angry with the performance of moderator Judy Woodruff. Though Woodruff is held in very high regard and has never been considered a showboat by her fellow journalists, many of the candidates didn't see it that way. They hated the "two-shots" that showed Woodruff walking over to the candidates to ask her questions, and they hated what they saw as her "high profile" during the debate. "She was in nearly every shot!" one candidate complained. One senior Democrat put it this way: "In general, the candidates do not want a moderator of greater stature than the candidates."

**"I don't want it paint-by-numbers. I want to break out."**
TOM BROKAW, *debate moderator*

Which means they are *really* going to hate the NBC debate. Though some of the moderators and questioners at prior debates have been people of considerable reputation and even some fame, Brokaw is the first superstar to moderate a debate this year, the first network anchor, the first moderator more recognizable than the candidates themselves. This gives him an advantage: Viewers see Brokaw as both likable and an authority figure and will not take it well if a candidate tries to be dismissive of him or slide away from his questions. And though Brokaw recognizes the debate is about the candidates and not about him, he does intend to facilitate things by getting in the candidates' faces when necessary. "I hope to have some surprises in the two hours," he says. Though some candidates may not like this, those close to the negotiations point out that the candidates have changed their desires with the political climate.

"At first, most of the candidates wanted tightly controlled



**STAGING.** Freelance set designer Eddie Knasiak oversees the painting of lecterns in New York (left). Above, producer Marian Porges discusses the proposed floor plan for the debate during a meeting at NBC headquarters in New York. Right, NBC's political director, Elizabeth Wilner, checks her ever present BlackBerry during a walk-through at the Polk County Convention Complex in Des Moines.

formats in which the candidates could not attack each other," one source said. "Then, as [Howard] Dean began emerging as the front-runner, they wanted a loose format so they could be free to attack him." The candidates also wanted opening and closing statements, which tend, in the view of many television professionals, to make the debates even duller. And most debates have been without them thus far. This, however, is about to change. "It's getting too close to the wire," one campaign official argued. "The stakes are too high. In a few weeks, people are going to start voting. What if you get beat up during the debate and don't get a chance to respond? What if you make a mistake? You need a closing statement to mop up the blood." So in Des Moines, there will be closing statements.

The candidate complaints come in not just after each debate but also during the debates, with the staffs calling network executives to complain about how their candidates are not getting enough time on the air. And they might complain during the Iowa debate, too. "We have made a good-faith pledge to try to provide roughly equal time," an NBC source says, "but it's close to the beginning of the primaries now, and anything can happen."

"I want it as free form as possible," Brokaw says at the meeting. "If you get into a metronome and buzzers and 'It's Mr. [Dennis] Kucinich's turn; it's Carol Moseley Braun's turn', then it's not engaging." Elizabeth Wilner, 33, the NBC political director, who has obtained three debates for NBC this year, asks Brokaw whether the candidates should be told that they, too, have the ability to interject and be free form. "They should trust me to run the show," Brokaw says. "I don't want it paint-by-numbers. I want to break out of that."

Later, in his comfortable but modest-size office, filled with family pictures, awards, and memorabilia, Brokaw recognizes that candidates do hate surprises. "But, you know," Brokaw says, "that's part of the risk that they have to take. I mean, part of our job is to act as the advocate of the audience and the voters and try to draw them out so that voters don't get just an infomercial. Why give up two hours of your time as a viewer if you think you are going to get one canned campaign speech after another? It's hard to convince campaigns of this, but it's in their interest, frankly."

## BRAND ME

There have probably been more presidential debates this year than any other year in modern presidential history. And it's not just because there's a crowded field of candidates—there have been crowded fields in the past—or because of any overwhelming hunger on the part of the public to see more political discourse. The most likely reason is branding. Whether it is a state party like the South Carolina Democrats, an interest group like the Children's Defense Fund, or a network like NBC, they all increase their visibility, their prestige, their clout by hosting or sponsoring a presidential debate. Which is why the

networks are willing to spend between $300,000 and $400,000 to put one on the air. In return, however, they want to make sure that viewers know who they are, which is why the debate sets have become backdrops for logos. At a debate in New York sponsored by CNBC and the *Wall Street Journal,* the logos were so ubiquitous that the candidates complained to the DNC. The logos will be fewer in Iowa, but the standard, one NBC executive said, "is we really want viewers to see an MSNBC logo when they see a candidate on the screen." There will be logos in the background, a painted logo on the stage beneath Brokaw's feet, and an MSNBC logo burned into the broadcast picture so nobody can use a clip without giving the proper credit. They don't call it branding for nothing.

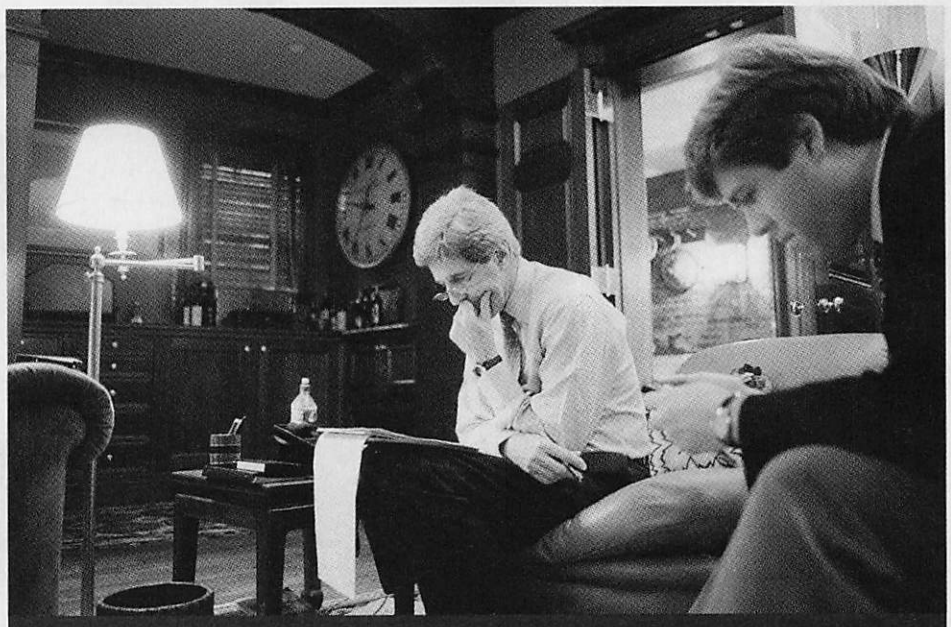
Mike Lukasiewicz, 46, executive producer for NBC news specials and special projects, has a corner office that offers a nice view of the ice skaters at Rockefeller Plaza. There is a trade-off, however: All day long he has to listen to the same Christmas carols endlessly repeated. And they are in the background as another debate team assembles, this time to discuss not just branding but the exact configuration of the lecterns on the stage. Lukasiewicz wants the array to be in a tighter, somewhat more horseshoelike pattern rather than the usual crescent or straight line that other debates have used. This will not only place the candidates closer to one another in order to facilitate the hoped-for exchanges but will also make it easier for Brokaw to walk between them. On the other hand, if the horseshoe is too tight, Brokaw will not get sufficient chance to walk. "We don't want it too small, or Tom will just be pivoting," one executive says.

Four different diagrams of the set have been put together by freelance set designer Eddie Knasiak, with the lecterns in subtly different configurations. The degree that Brokaw can walk, pivot, and get close to the candidates is discussed at length. "We want a set that is Tom-friendly," one planner says.

One friendly high-tech gizmo NBC intends to use is a robotic spotlight system that will follow Brokaw wherever he moves. Brokaw will wear a sensor under his suit collar that will send a signal to spotlights that will track him without human controllers. But there is a problem: If Brokaw gets too close to the candidates, his robotic lights will conflict with the spotlights on the candidates. "Tom can't get closer than 6 to 8 feet," a planner says. That limit, however, is not acceptable to Lukasiewicz. He knows that even though the candidates may hate it, Brokaw may want to get as close to them as decency allows. And in a contest between technology and Brokaw, there is no contest. "I don't know how the lighting people solved it," Lukasiewicz says later, "but they solved it. If it's important around here, it gets fixed." Lukasiewicz has a goal that goes beyond mere lighting, however. "As a producer and a journalist," he says, "do I want this debate to make headlines? Sure. Do I want some candidate to say something he has never said before and make news? Sure."

## IOWAY

To the untrained eye, the upper hall of the Polk County Convention Complex in Des Moines is simply a vast, empty, echoing box. It has moveable walls and a speckled gray concrete floor that has some brown dribbles etched into it. These turn out not to be artwork, however, but accidents. "That's what happens when combines drop battery acid," Scott Hallgren, the event coordinator for the complex, says a little ruefully. NBC is not planning on bringing any farm machinery in here, however. And the most acidic item, Joe Lieberman, who, more than any other candidate, has used the debates to attack his fellow Democrats, has dropped out of the NBC debate, because he would rather campaign in New Hampshire than be on national television in Iowa. What NBC will bring in is exactly 906 seats, 800 of which will be distributed by the DNC to the party faithful. NBC actually wanted 200 fewer seats in the hall, because it did not want too vast a setting, but the DNC would hear none of it. Debate tickets are like currency, and in Iowa, a state with a Democratic governor, a Democratic senator, hundreds of Democratic activists, and the presidential campaigns themselves, there are lots of palms to cross.



**BONING UP.** Sen. John Kerry, preparing to cross verbal swords with the other candidates

To Marian Porges, 43, producer of NBC news specials, the room is not a mere empty box. When she looks at it, her expert eyes see what it will look like on debate night, which is why when others on her team call it the "room" or the "site," she always calls it the "Theater," and you can hear the capital letter in her voice. By the time NBC and a horde of technicians are done with it, that's what the room will look like: a theater with row upon row of seats, a 32-by-66-foot stage, a very elegant backdrop made up of 15 fabric panels with a snazzy flag design (and plenty of MSNBC logos) on them, and a horseshoe of modernistic lecterns. Porges's job extends far beyond the set, however. She also has to worry about moving the candidates around. She has to make sure they can get into the complex, get to their greenrooms, get to the Theater for the debate, and then to Spin Alley to schmooze the press. And because candidates have been known to wander off, she has a team of

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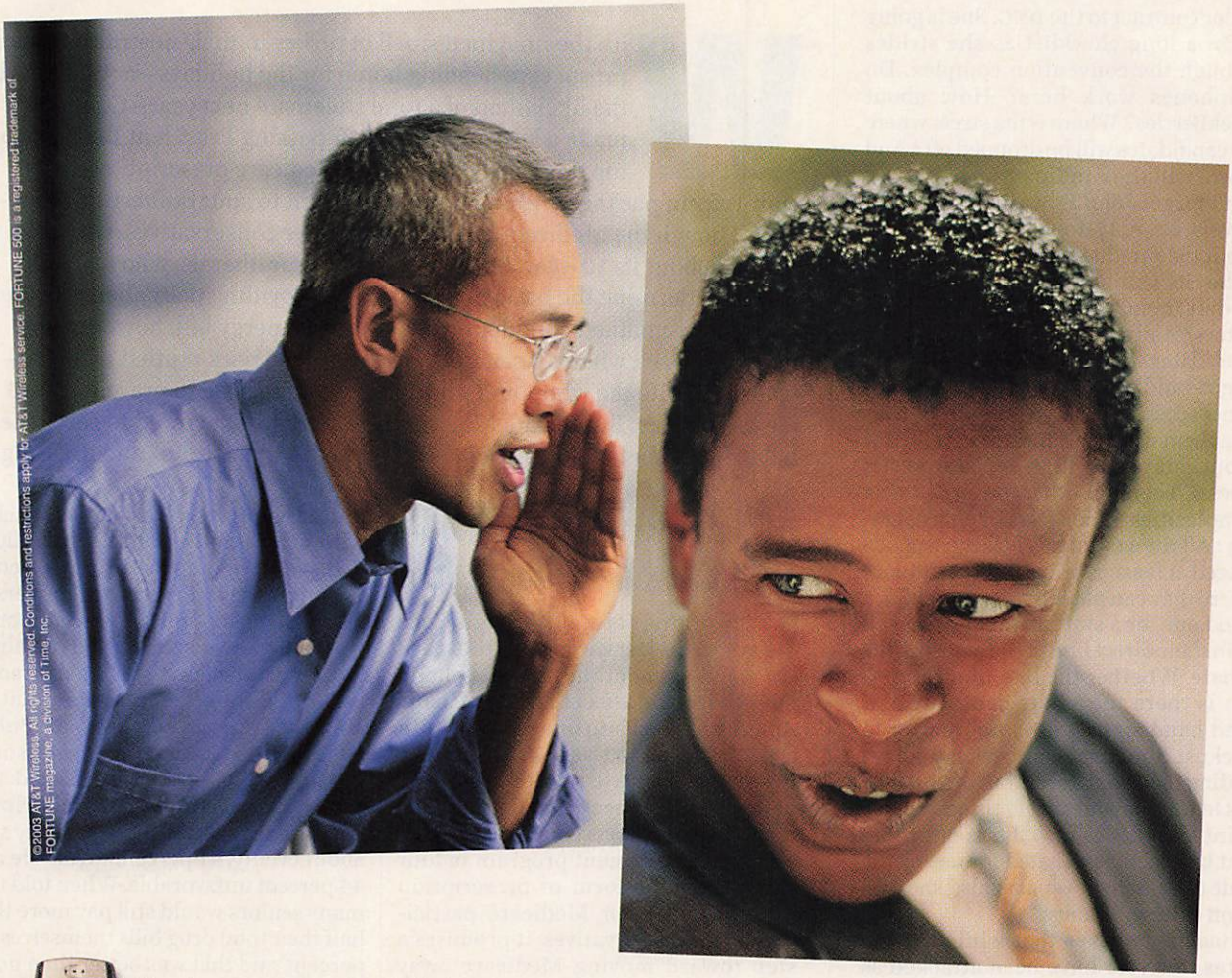

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herders assigned to them. "We will have four producers with walkie-talkies," she says. "And a channel on the walkie-talkies just for candidate movement." Eventually, Porges will produce a 40-item production schedule. Way down at Item 36 is: "Debate."

**Carrots, please.** Along with Porges on this inspection tour is Jenny Backus, 35, a Democratic debate consultant who is under contract to the DNC. She is going down a long checklist as she strides through the convention complex. Do cellphones work here? How about BlackBerries? Where is the street where the candidates will be dropped off? And where will the candidates park? (And don't forget John Edwards sometimes travels on a 47-foot bus!) And how about the satellite trucks? What streets is the city willing to close off to accommodate them? Are there any likely protesters? And how about catering for the candidates—Kucinich is a vegan, don't forget—and will they get high-speed Internet access in their greenrooms? "Let's give them a choice," Backus says. "How about catering *or* high-speed Internet access." There are other concerns, other complexities, other feats of choreography: All the candidates have been guaranteed at least one seat in the audience where they can place a spouse, a child, a loved one, or a staff member, who will be in their direct line of sight during the debate. Whether the line-of-sight person is there to radiate confidence or send hand signals does not matter to Backus. She just has to worry about finding those eight seats out of 906. She has to worry about a lot of things. At one point she strides into the men's room that has been designated for use by the male candidates. "Ten urinals," she says upon exiting. "Plenty."

Backus believes that while the debates this year have been attacked as being meaningless by some of the candidates themselves, they are missing a point. "You tune in, and you see a preacher, a general, a woman, senators, a member of Congress, a former governor, Jews, half-Jews, Catholics, Protestants, African-Americans," she says. "Just seeing that field on stage sends a message that is good for this party."

Though the DNC's role in brokering the debates is now over, more network debates undoubtedly will spring up in the months ahead. "The networks are approaching this campaign like it's a war," Elizabeth Wilner says. "And they want to own it like they owned the war coverage." ●

# CAPITOL GIFTS FOR THE HOLIDAY

With the imagined smell of turkey in their nostrils and the prospect of heading home for the holidays—not to mention the likelihood of a total stalemate next year—Congress made a last-minute stab at passing President Bush's two top domestic priorities: a Medicare prescription drug-cum-reform package and an energy bill meant to spur domestic production. Though the Medicare bill pleased neither conservatives, who complained about its 10-year, $400 billion cost, nor liberals, who feared it would undermine the basic program while providing paltry benefits, Republicans remained confident of victory. The energy bill, however, suffered a setback when 40 senators choked on the pork-stuffed measure—which, despite the whopping price tag, would do little to prevent future power outages. But Senate Majority Leader Bill Frist vowed to serve the bill up again before lawmakers head home for their turkey and dressing.

## A MEDICARE PRESCRIPTION THAT'S HARD TO SWALLOW

Working its way through Congress last week was a 681-page document the size of a phone book that could affect the lives of many Americans deep into this century. With a $400 billion, 10-year price tag, the measure attempts to straddle both ends of the political spectrum. For liberals, it promises the largest increase in a government entitlement program in four decades in the form of prescription drug coverage for Medicare participants. For conservatives, it promises a step toward moving Medicare away from traditional fee-for-service coverage and toward the kind of managed care most employed people now have.

In striving to meet those disparate goals within its still-huge price tag—while also appeasing hundreds of other diverse interests—the legislation has earned a dubious distinction: Almost nobody likes it. Its provisions include increased payments to physicians, promises of coverage in rural areas, subsidies to the insurance industry so it will take on high-cost elders, a ban on allowing Medicare to negotiate drug prices on behalf of the full block of 39 million recipients, and payments to some large employers so they won't pull the plug on private health benefits for retired employees. It's complex, packed with deals—and a political minefield. "This is an ugly contraption of a compromise," says Princeton University healthcare economist Uwe Reinhardt.

And the more seniors find out about its details, the less they like it, according to the Kaiser Family Foundation and the Harvard School of Public Health. Robert Blendon, professor of health policy at Harvard, asked 376 senior citizens their opinion of House and Senate bills last summer. They split about evenly, 41 percent favorable and 44 percent unfavorable. When told that many seniors would still pay more than half their total drug bills themselves, 37 percent said that was better than nothing. But 56 percent said Congress should go back to the drawing board.

The trouble is, few people of any age really understand the myriad changes on the horizon. Not until some time in 2005 will seniors get letters asking them if they want to opt in to the drug benefit portion of Medicare the next year. What they will be offered bears scant resemblance to the drug coverage employed Americans are used to—a fixed, generally low copayment.

**A doughnut.** What the new coverage will do takes some calculation. (A calculator can run your numbers at *kaisernetwork.org/static/kncalc.cfm.*) The average yearly cost of prescription drugs for those over 65 is estimated to

LARRY DOWNING—REUTERS

**DUBIOUS.** **Some senior citizens were less than thrilled by their promised drug benefits.**

be $3,160 by 2006, the year the bill would kick in. With the new benefit, after paying the $250 deductible, monthly premiums of about $35, and 25 percent cost-sharing up to $2,250, the typical Medicare patient will end up spending $2,080 for the year, saving about $1,000. Seniors then pay the next $2,850. When total drug costs reach $5,100, the Medicare policy kicks in again, this time with a 5 percent copayment. The gap in coverage has come to be called the "doughnut hole."

If one's drug costs are extremely high, say $12,000 a year, out-of-pocket costs would be only $4,365. Other elements of the new law, such as discount cards or medigap policies, further complicate the calculation. And while the premium would be waived for some low-income seniors, others could lose drug benefits from state Medicaid programs.

Certainly, retirees who get generous health benefits from former employers don't want to lose them. So the bill includes incentives to encourage some large employers to maintain retiree benefits. But the 1.3 million members of the American Federation of Teachers are worried, because part of the subsidy excludes public-sector employers.

The reform part of the package—which many Democrats see as an attempt to destroy Medicare and Republicans see as an attempt to introduce market competition—doesn't kick in until 2010. What began as an attempt to introduce managed care into the mix nationwide has been whittled down to pilot programs in six as yet unnamed regions.

The concern among those who say HMOs have not worked for Medicare recipients is that the private sector will attempt to "cherry pick" the healthiest seniors. "There will be extreme aggressiveness by insurance companies to enroll healthier, younger seniors," says Robert Hayes, president of the Medicare Rights Center. And if traditional Medicare becomes a fallback system for only the oldest and sickest, premiums will rise beyond the means of many. "Medicare would go into a death spiral," says Reinhardt.

Those who say Medicare needs a complete overhaul are equally concerned that the program will grow out of control. "This is the worst of all possible worlds," says Robert Moffit of the Heritage Foundation.

Even AARP, whose support of the bill went a long way in keeping it alive last week, sees it as simply better than nothing. "We believe this bill is inadequate and needs to be improved. But it will provide some relief to millions," says David Certner, director of federal affairs for AARP. *–Susan Brink*

### RX FOR MEDICARE

At a 10-year phase-in cost of some $400 billion, the bill would provide:

**Medication coverage.** For the next two years, some low-income seniors will get a $600 voucher. In 2006, seniors can buy into a limited drug benefit for about $35 a month.

**Medicare options.** In 2010, pilot programs in up to six areas begin offering seniors competitive choices in health plans.

**Incentives.** A small raise for doctors; subsidies for insurers, some large firms.

## A MAALOX MOMENT DOOMS A FAT-LADEN ENERGY BILL

It turned out to be just too much pork to digest. Congressional leaders crafted an energy bill that wouldn't have freed the nation from foreign oil dependence, prevented power blackouts, or held down home-heating costs. But it would have delivered $25.7 billion in federal subsidies to industry. In a move that opponents found particularly hard to swallow, the bill would have let petroleum producers off the hook for cleanup of the troublesome drinking water pollutant MTBE. And it would have loosened the fetters on mergers and acquisitions that have reined in public electric utilities since the Great Depression.

Supporters fell two short of the votes needed in the Senate to end a Democratic filibuster of the first overhaul of national energy policy in a decade. Another vote could come this week, depending on the success of Republican maneuvering. Still, it's a blow to the Bush administration, which has spent nearly three years pushing for a plan. Even last August's massive power blackout couldn't shock Congress out of gridlock. "Energy policy is a big hole," said New Mexico Sen. Pete Domenici, one of the legislation's architects. "We keep dropping things into it, but we never solve it."

**Corny.** Opponents said that a few too many goodies were dropped into this package. Aileen Roder of Taxpayers for Common Sense called it "a pirate's booty of frivolous projects . . . to grease the wheels of the legislative machine."

The corn alcohol fuel, ethanol, was a lubricant that helped numerous votes slide into place, as farm-state Democrats, like Senate Minority Leader Tom Daschle, abandoned their party to sup-

port home industry. The bill would have spent $2.9 billion to double production by 2012. But the largest subsidies would have gone to oil and natural gas. GOP legislators never mustered support for the longtime goal of drilling in Alaska's national wildlife refuge, however.

The provision that more than any other killed the bill was a clause protecting oil companies from lawsuits over the gasoline additive MTBE, which has seeped into drinking water from New England to California. MTBE helps gas burn cleaner, but it has become a pervasive groundwater contaminant. Cities and states, particularly New Hampshire, have aggressively pursued the oil industry in court to pay for cleanup. The Granite State's two Republican senators joined Democrats to oppose the bill.

The bill's supporters said it would help prevent another power blackout like the one that cascaded across eight states and Canada in August. Indeed, it would have subjected companies to penalties for violation of previously voluntary reliability standards. But electricity grid operation would have remained divided among numerous companies, so the bill did little to prevent a recurrence.

Labor unions balked at the bill's provision to repeal the Public Utility Holding Company Act, which placed controls on utility mergers and acquisitions in response to the Middle West Utilities scandal of the 1930s, the Enron of its day. Investor Warren Buffett had indicated he would invest $15 billion in the utility sector if the law was repealed.

No nuclear power plants have been proposed in the United States since 1979, but Congress was prepared to hand out $6 billion in tax credits for approximately six new power plants. The bill's largess extended beyond the energy industry, prompting Republican Sen. John McCain of Arizona to deride the subsidies for "Hooters and polluters." It would have spent $227 million to help finance "energy efficient" construction of shopping malls, including one in Shreveport, La., featuring the restaurant renowned for its busty waitresses. And it would have waived $48 million in tariffs on energy-saving ceiling fans from China, much to the benefit of top seller Home Depot. *–Marianne Lavelle*

## TAKING CARE OF, AHEM, BUSINESS

CHRIS MADDALONI—*ROLL CALL*

**Sens. Rick Santorum (left) and Bill Frist reflect the Hill's mood.**

Thanksgiving was so close that some people were already talking turkey, but Congress remained in Washington negotiating the fine points of Medicare reform and a national energy strategy. By week's end, all the horse-trading and arm-twisting had produced some confidence that Congress might yet pass an energy bill, institute a prescription drug benefit for seniors, and finish work on this year's federal budget—and do it all before the holiday break.

Why the sudden urgency? Some lawmakers said it is due to the sense that this is the last chance to get anything important done on Capitol Hill. Election Day, after all, is just 11 months away. "If you want to get an energy bill, I would say now is the time," mused Rep. Mike Castle, a Delaware Republican. "Nothing is going to happen next year."

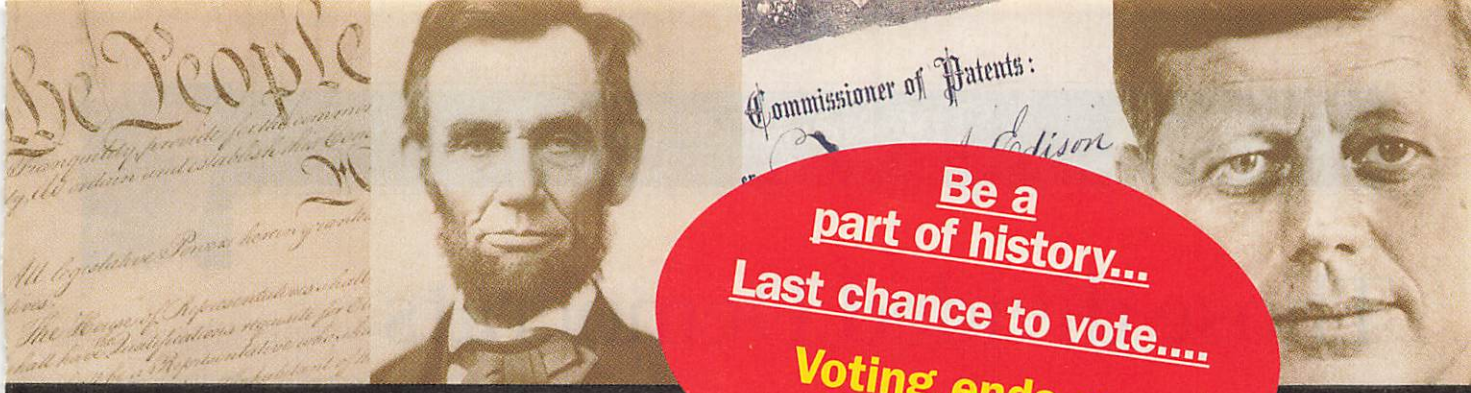
What resulted was an amalgam of unholy alliances and fair-weather friends, and political calculations based not on partisan politics but on what the voters wanted back home. With Medicare, of course, it was clear they wanted *something*.

In the process, though, expectations were turned on their head. The 681-page Medicare proposal's consequences would be monumental. But its standing as a political document was thrown into stark relief in New Hampshire last week when the Democrats running for president savagely attacked the leadership of the 35 million-member AARP for endorsing the largely GOP proposal. The attacks came at a forum hosted by AARP the day after the group announced its support for the Medicare plan. The guests were not kind to the host. "I'm not proud of what the AARP has done with this bill," said North Carolina Sen. John Edwards. Sen. Ted Kennedy, who has long been an AARP ally, actually led a rally against the organization.

**"Nut cakes."** In the House, where leaders can almost always impose their will, the leadership found itself unsure that it could pass Medicare. And the problem wasn't Democrats; it was conservative Republicans, concerned about the $400 billion cost of the proposal. "You can't talk to those guys; they are nut cakes," says Rep. Amo Houghton, a moderate Republican from upstate New York. "They are absolute purist, line-in-the-sand kind of guys, but that is not how the world works. Democrats do it, too."

The enormity of the moment was driven home when Newt Gingrich, one of the high priests of the shrink-government movement, took to the op-ed page of the *Wall Street Journal* to urge reluctant conservatives to support the measure. In language once reserved only for Democrats, he warned: "Obstructionist conservatives can always find reasons to vote no, but that path leads right back into the minority."

The current minority was simply trying to hold it together. Asked if House Democrats who voted for the Medicare bill could face reprisals, House Minority leader Nancy Pelosi quipped: "I am not at liberty to reveal the timing or nature of the repercussions." There was laughter to suggest she was joking. But, remember, Election Day is less than a year away. *–Terence Samuel*

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# Those divided Democrats

THE COUNTRY IS CLOSELY DIVIDED between Republicans and Democrats, but it's not a symmetrical division. The Republicans are united and the Democrats are divided. Republicans are solidly behind George W. Bush. Democrats are about evenly divided on issues like military action in Iraq and gay marriage (a possible election-year issue given the decision of the Massachusetts Supreme Judicial Court last week). About a third of all Democrats give Bush a positive job rating.

The Democrats seem divided roughly evenly between Bush haters and people who have mixed feelings about the president. Howard Dean has made himself the favorite for the Democratic nomination by forging a bond with the Bush haters through his early and consistent opposition to military action in Iraq. His campaign has used the Internet brilliantly to establish personal links with 230,000 contributors, 505,000 supporters—orders of magnitude more than any other Democrat. Other candidates have responded by imitating his scathing contempt for Bush and all his works, in the hope of peeling off his supporters and preventing him from running away with the race by winning the Iowa caucuses and the New Hampshire primary. The Democratic race has become a contest for the left-most 20 percent of the electorate.

**The un-Dean.** The other Democrats have had little success. Dick Gephardt does have a narrow lead in Iowa, but winning the caucuses there means turning out people on a cold Monday night, and it's not clear that Gephardt's supporters can match the enthusiasm of Dean's. Dean has a wide lead over John Kerry in New Hampshire and runs at or near the top in national polls. So Dean's competitors have started to take a different tack. At the November 15 Jefferson-Jackson Day dinner in Des Moines, Kerry and John Edwards said that the party needs a nominee with answers, not anger. Gephardt and Joe Lieberman have struck similar notes. They hope to be the un-Dean—the candidate who survives Iowa, New Hampshire, and the gantlet of February 3 contests and then faces off against Dean in the big states starting with Michigan February 7. Dean campaign manager Joe Trippi expects that someone will emerge as the un-Dean. And it's not clear that in the big states Bush haters will outnumber more ambivalent Democrats. Either Dean or the un-Dean, whoever he turns out to be, could win.

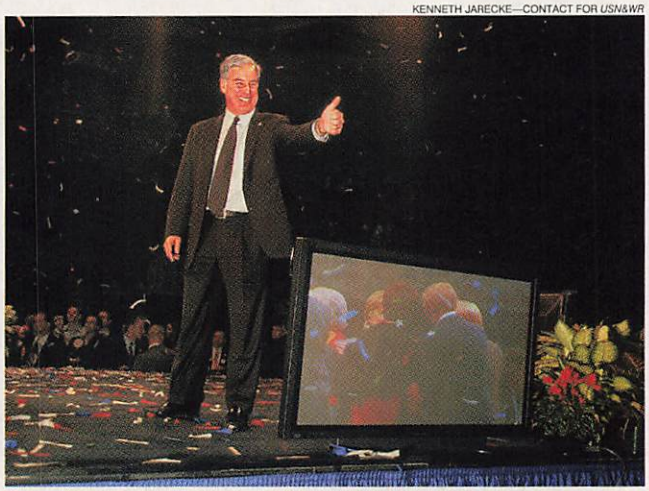
But Democrats will have a problem either way. If the un-Dean wins, Dean's enthusiastic supporters will be bitterly disappointed. Some will not want to vote for a Democrat who voted for military action in Iraq. The Green Party nominee, whether Ralph Nader runs or not, could easily exceed the 3 percent Nader won in 2000. That would hurt with the electorate this closely divided. Just ask Al Gore.

The Democrats' problem will be different if Dean is nominated. Their problem will be with American exceptionalism. That is the idea, shared by most Americans, that this country is unique and special, with unique virtues and special responsibilities—a city on a hill, as John Winthrop and Ronald Reagan put it, with the responsibility to spread freedom and democracy around the world. Franklin Roosevelt and Harry Truman, John Kennedy and Ronald Reagan were all American exceptionalists. So, as we have seen with ever increasing clarity, is Bush. Dean doesn't seem to be, and neither do most of his followers. When they say they want to take their country back, they mean they want the United States to take its place as just one of many nations, with no claim to moral superiority, heeding the cautions of France, Germany, and Russia; deferring to the United Nations or NATO; seeking the respect of the protesters in the streets of London or the opinion writers in *Le Monde*.

Bill Clinton, with his political genius, managed to straddle his party's division on American exceptionalism by speaking eloquently about America's commitment to freedom and democracy on some occasions and apologizing for America's past sins on many others. Howard Dean doesn't seem to have this gift. Americans have seldom, if ever, voted for a presidential candidate who does not seem to believe in American exceptionalism. Dean's nomination would give them a clear choice in 2004. ●

It could come down to a contest between Dean and the un-Dean, but after that, what?

KENNETH JARECKE—CONTACT FOR *USN&WR*



**LEADER OF THE PACK. The former Vermont governor, at the recent Jefferson-Jackson Day dinner in Des Moines**

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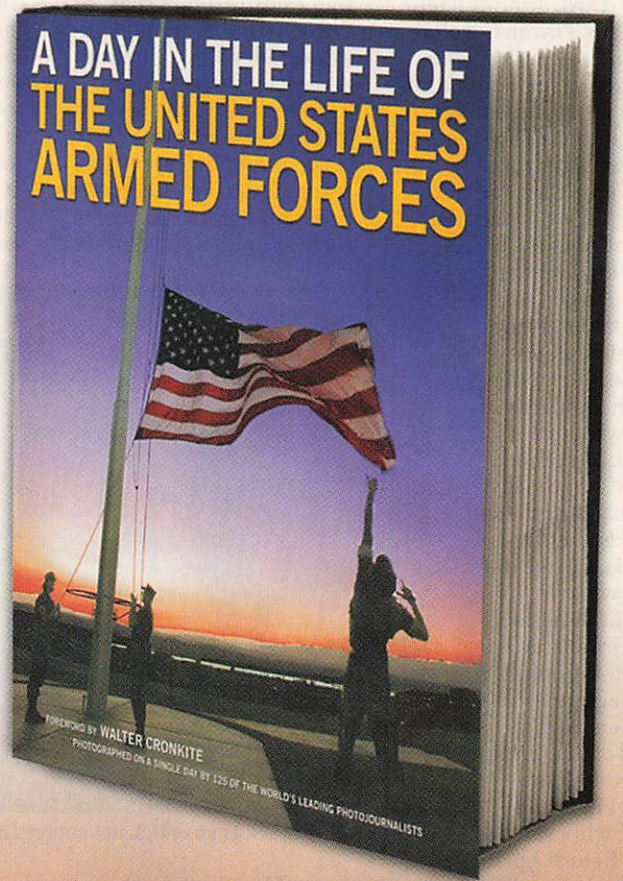
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LETTER FROM IRAQ

# The battle in the blue yonder

BY BAY FANG

BAGHDAD—On April 7 this year, Ismail Mohammed (not his real name) drove around Baghdad in his Toyota Corolla with an SA-7, a shoulder-launched surface-to-air missile, in the back seat. He stopped to shoot at the A-10 Thunderbolt dropping sound grenades and flares through the sky over the city, then at an Apache swooping over the rooftops. As a senior commander in the Iraqi air-defense effort, he helped distribute hundreds of these weapons—sometimes called "SAMs"—in the last-gasp effort of the former regime. "In those last three days of the war, we brought in all the SA-7s from stores around the country into Baghdad and put them in the hands of whoever wanted to fight—fedayeen, intelligence, whoever," he says. "Before April 7, I never shot an SA-7 before. But on April 7, I shot 12."

Or tried to, anyway. None of the 12 actually fired. "They were all bought on the same contract with Russia in 1983, and the batteries were all dead," says Mohammed. He believes the guerrillas are now are using the same weapons. "All the resistance has to do now is find new batteries. [SA-7s] are very easy to learn to use. One good teacher could train 50 to 100 people."

It's a dire warning. Since November 2, four U.S. helicopters have gone down over Iraq, killing 39 soldiers. And though shoulder-fired missiles have been confirmed as the culprit in only one of the incidents, there's little doubt that these weapons are now the newest, deadliest threat to American forces in Iraq. The worsening security environment underscores the risks in rushing a political transition to an elected government here. The attacks have left pilots shaken—and scrambling both to change tactics and make sense of the risks they take daily.

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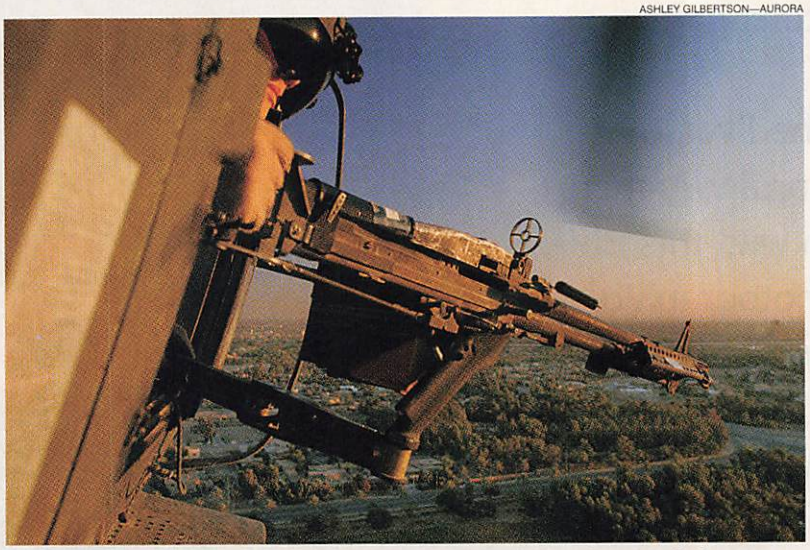

**RISKY BUSINESS.** Loss of U.S. helicopters has left pilots and crews shaken.

The airfield at Baghdad International Airport is packed with helicopters ready to be loaded for missions on a moment's notice. Pilots in khaki coveralls hover around the powerful machines. Chuck Juul, a 34-year-old Black Hawk pilot from Kansas, never says he is scared. "When you're up there at night, looking through [the night-vision] goggles, you see tracer fire all the time," he says. "I've seen a SAM being launched in the distance, the smoke trail looking like a giant Roman candle." Now, Juul says, he and his colleagues fly faster and lower and vary their routes to try to avoid being hit. "When we first got out here, maybe we were lulled into a sense of complacency," says Tim Vaught, a fellow pilot. "But the events of the past month put a fine sharp edge on a once dull knife and awakened everybody."

It has also awakened resentment. The night after the most recent incident, when two Black Hawks collided and crashed in the northern city of Mosul, the airmen of the First Armored Division, stationed at the Baghdad airport, gathered to talk about what went wrong. "People were pissed off," says one of the soldiers who was there. Partly, this was because they felt the missions they flew did not warrant the risks involved. "Sometimes we're just flying some guy who's late for a meeting or doing sightseeing tours. One of the first reactions was, 'What the hell are we doing flying these bulls - - - missions?' "

**Countermeasures.** The second issue was the defensive equipment they had on the planes. Black Hawks and Apaches belonging to the conventional Army, which make up the vast majority of those flown in Iraq, are not equipped with flare dispensers, which help confuse infrared-guided weapons like SA-7s. An Army official says Black Hawks and Apaches actually have systems to defeat the missiles that are "newer and more up to date" than the flare dispensers, but out here on the firing line, the pilots aren't buying; they want flare dispensers. "It's a question of money," says one pilot. "If they were buying a radar detector for a car, the Army would buy the $89.95 one, not the $300 one."

Back at the airport, Juul and Vaught prepare to head off on another mission. Juul says he was in the same battalion as some of the pilots who died recently. "It hits a little closer to home when you know one of the guys, because some of them I considered better pilots than I am," he says. "Most pilots have that invincibility attitude; they don't really think it could happen to them." His colleague Vaught says quietly that he is sure of only one thing. "It won't be me. I promised my wife and son. It won't be me." ●

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# FACING THE UNFACEABLE

## Are the twin attacks in Istanbul evidence of a resurgent al Qaeda?

BY KEVIN WHITELAW

Britain's consulate in Istanbul sits on a busy corner in a historic neighborhood of narrow, twisting streets. It must have been an inviting target for the driver of the explosives-laden delivery truck. The American consulate down the street had already moved to a safer location on the city's outskirts this summer. The truck's explosion demolished the entrance to the consulate and ripped the facades off several buildings nearby. At the market across the street, bloodied victims ran past stands of neatly stacked fruits and vegetables, somehow untouched by the blast. The scent of ammonia, identified by Turkish police as one of the bomb's ingredients, hung in the air. Moments later, an eerily similar scene unfolded across town, where another suicide bomber struck the British-based HSBC Bank.

Turkey is no stranger to terrorism. But last week's bombings came just five days after two other suicide bombers hit Istanbul synagogues. In all, over 50 people were killed, including Britain's consul general. Hundreds more were wounded. At least two of the bombers were identified as Turkish citizens, forcing Turks to confront the possibility that a strain of violent, intolerant Islamic radicalism has taken root in their democratic and secular nation. "These attacks, inherently and implicitly, can threaten the social fabric of Turkey," says Cengiz Candar, a Turkish political analyst. "It is an attack on the model that Turkey signifies and symbolizes, in the sense that Turkey is the only democracy functioning within a Muslim society."

Despite the Turkish identity of at least



PHOTOGRAPHS BY GEORGE GEORGIOU—PANOS

**AFTERMATH. The bombing of the British consulate left 16 dead, scores wounded, and many anguishing over their security.**

some of the bombers, the bombings bear all the fingerprints of the al Qaeda network. The timing of the bombings, with President George W. Bush on his state visit to London, suggested a new al Qaeda effort to attack Britain because of its collaboration with American forces in Iraq, although British Prime Minister Tony Blair discounted this possibility. U.S. intelligence officials tentatively blame al Qaeda but dismiss al Qaeda's claims of responsibility for the attacks. "They made a decision that they will claim everything they can and that way keep us off balance," a senior U.S. official tells *U.S. News*. "It's a decision that costs them nothing, and they think they will muddle our intelligence gathering or at least delay us."

Terrorists, including al Qaeda, have long used Turkey as a key transit point. But *U.S. News* has learned that Turkey has also been high on al Qaeda's target list for some time. Turkish authorities have thwarted several attacks attempted by al Qaeda operatives over the past couple of years, according to a senior U.S. official. "People were surprised by the sequence and surprised by the scale," the official says, "but not surprised that Turkey would face this kind of risk."

**"A nice axis."** The spate of bombings helps feed the perception that al Qaeda's capabilities are increasing once again, despite America's continuing war on terror. "Turkey's attractiveness may have been more geographical because it raises the specter of violence in Iraq spreading outwards," says Bruce Hoffman, a terrorism expert at Rand, a defense-oriented think tank. "From al Qaeda's perspective, this may have formed a nice axis from Baghdad to Istanbul."

More broadly, the head of Germany's foreign intelligence service, August Hanning, warned last week that the group has "regenerated." In particular, al Qaeda has become increasingly decentralized and difficult to target, as more obscure affiliated groups and other individuals trained in Afghan camps are able to move around and plot without being detected. U.S. intelligence officials note that al Qaeda cells and affiliates appear to have been granted an increasing amount of local autonomy to operate. "The attacks are coming more from cells than caves," says one intelligence official. Given this, it is no surprise that U.S. officials are warning that more attacks are likely, in Turkey and beyond. ●

*With Yigal Schleifer in Istanbul*

# HASSLE HOLIDAYS

## Flying home? Get set to wait. And... wait

BY SAMANTHA LEVINE

Sarah White is flying from Washington, D.C., to Idaho to see family for Thanksgiving *and* Christmas. But the specter of airport security hassles doesn't faze the 28-year-old—she has the post-9/11 drill down. She'll get to the airport early, wear metal-free shoes, and check bags to avoid delays. "I've never missed a plane," she says confidently.

White is just the kind of prepared traveler the Transportation Security Administration loves—and preparation may be crucial in the weeks ahead. More Americans are flying, but the supply of security screeners checking baggage is shrinking. So this holiday season could feature lots of airport bottlenecks.

Air traffic still hasn't returned to pre-9/11 levels, but "things are going in the right direction," says Southwest Airlines spokesman Ed Stewart. During this year's Thanksgiving-Christmas period, there will be 1.1 million more seats on nearly 31,000 more flights than in 2002, says OAG, a company that tracks flight schedules. That's the good news.

The bad? The TSA, created to federalize airport security after 9/11, has been under pressure from Congress to trim its budget, and it cut its airport-screener staff from 55,600 to about 48,300 between March and September. "We are expecting long lines," says David Stempler, president of the Air Travelers Association. "There is a possibility that it will be worse this year due to fewer screeners." Chicago's O'Hare airport went from 2,082 screeners down to 1,885. Atlanta's Hartsfield dropped from 1,238 screeners to 1,090, and officials there are expecting 10 percent more passenger traffic for Thanksgiving week this year than last.

SCOTT GOLDSMITH FOR *USN&WR*

**LINE DANCE.** Air traffic is up, and screeners are down.

The TSA does have a plan. It's hiring part-time screeners—3,000 so far—to help staff checkpoints. Some airports will open extra security lanes for the holidays. Others will import screeners from nearby airports that aren't so busy. But sometimes, says TSA spokesman Nico Melendez, "there is nothing we can do" about lines. Miami International Airport, for instance, could see security lines of an hour or more during the holidays. Miami passengers are toting nearly three times as many bags as the average U.S. traveler, usually because they're bringing items back to homes in Latin America. This year's other trouble spots are likely to be Denver, Los Angeles, New York (La Guardia, JFK International, and Newark), and Chicago (O'Hare and Midway), says Amy Ziff, editor at large for online travel site Travelocity.

So do yourself a favor, experts say: Get to the airport an hour and a half to two hours before your flight. Then empty your pockets, put your shoes and coats through the X-ray machines, remove laptops from their cases, and leave presents unwrapped and bags unlocked. That could buy a few precious minutes—and save you the indignity of getting pulled from the line for a "secondary" screening. ●

## WHO'S GOING TO CHECK ALL THOSE BAGS ANYWAY?

The Transportation Security Administration has been around for just a couple of years, but it may look like a very different place a year hence. By November 2004, the nation's 431 airports will have the chance to opt out of the TSA's airport-screener program.

That's because the law that created the TSA has an escape hatch. Airports that can prove the change wouldn't harm security can hire private companies—under federal supervision—to take over security. It's too early to tell how many airports will do it: The TSA is still developing the process and criteria by which the airports could make the switch, and it's the TSA that will probably decide.

**Safety first?** There's no lack of interest in going private. The TSA has been grilled over its training programs, security lapses, and technology installation glitches. Carter Morris, vice president of transportation security policy at the American Association of Airport Executives, says private companies "could provide an opportunity to change for the better." A barrage of new reports could influence those decisions. The first will compare federal screeners' effectiveness with that of private screeners who remained at five U.S. airports under a pilot project. In January, the Homeland Security Department's inspector general will release its evaluation of the pilot program, and the General Accounting Office will report on the TSA in April. Says Gary Burns, spokesman for Rep. John Mica, chair of a House aviation panel: "Airports will go with what they see as the safest option." *–S.L.*

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# Avoiding democracy

SOME ADMIRE THE GAY-MARRIAGE ruling in Massachusetts. Some don't. But surely the heart of the story is the stupefying arrogance of the state's Supreme Judicial Court. If you are going to stretch a state's constitution beyond all previous understanding and impose what many people believe is a fundamental redefinition of marriage, you don't do it in a 4-to-3 vote. There is no consensus among Massachusetts voters for such dramatic change. On a liberal court, thought to be favorable to gay issues, there was not even a consensus among the seven judges who pondered the issue for more than a year. The three dissenters expressed some sympathy for gay arguments but also some serious legal doubts. Justice Martha Sosman wrote that as a matter of constitutional jurisprudence, "the case stands as an aberration. To reach the result it does, the court has tortured the rational basis test beyond recognition." No matter. Chief Justice Margaret Marshall rammed the ruling through anyway.

In the manner of modern judicial elites, the four judges rode roughshod over the legislature and the voters. They shut down the compromise option of allowing gay civil unions. They constructed the ruling so the legislature could address the issue in only one way—by ratifying what the court demanded. "Do it our way, or we'll do it ourselves" was the clear message. No, the judges wouldn't want to leave open the possibility that democracy might break out in the legislature. The court also seemed to close the door on being overruled by a constitutional amendment. It ordered the legislature to act in accordance with its wishes in 180 days, and by law the constitution can't be amended in less than three years. By then thousands of gays will have married. The four went further than any other state court has gone. Courts in Hawaii and Alaska approved gay marriages but made no attempt to hamstring legislators. In both states, legislatures passed constitutional amendments limiting marriage to heterosexual couples.

How could the four have missed the obvious lesson of *Roe v. Wade*? The U.S. Supreme Court's abortion decision, imposed out of the blue with flimsy constitutional cover, short-circuited debate that was still in its early stages. It took the issue out of democratic politics and sparked 30 years of social turmoil. It gave everything to one side of the debate, nothing to the other, and made a European-style compromise impossible by its arrogant and constitutionally dubious "fundamental right" ruling. It assured rage by making its decision democracy-proof—as antiabortion forces quickly learned, the ruling could not really be modified by democratic decision making. Well, here we go again. Although a serious debate on gay marriage has not yet taken place, the short-circuiting process is already far advanced, complete with attempts to bar the civil-union compromise and to make a constitutional amendment almost impossible. Once again, no consensus and no broad debate. And just as with the abortion decision, a court is summoning up enormous opposition by foreclosing normal democratic procedures.

**Glamour factor.** Why do judges behave this way? One reason is "landmarkism." The loudest applause from the legal academy tends to come after a far-reaching allegedly progressive decision unsupported by public opinion and with no real basis in the U.S. Constitution or case law. No judge gets to be admired by the legal and media elites by simply following law and precedents. No glamour there. You have to make something up. *Brown v. Board of Education* in 1954 was a good and necessary decision, but it created the monster of "landmarkism." It also deeply affected left-right politics. As the left gradually despaired of attracting a majority of voters to its programs, it opted for a strategy of going around the voters by relying on judges to impose liberal outcomes. This liberal end-run around politics is what the current battle over judges is all about.

"'Do it our way, or we'll do it ourselves' was the clear message."

Then, too, the mind-set of media and judicial elites is dominated by a very simplistic view of the gay marriage issue—that it pits bigotry against valiant attempts to include an oppressed group. That pared-down view of the issue is the reason why very serious concerns are not on the elite radar screens. The Massachusetts decision depicted marriage as an intimacy choice for individuals. Procreation and child rearing, central to a prevailing view of marriage for most of western history, pretty much disappeared in the decision. Chief Justice Marshall even played this point for laughs in oral arguments, asking whether a married couple should be forced to divorce if they are childless after 10 years. Chuckles ensued. This attitude almost guarantees that gay marriage, unlike civil unions or benefits for committed gays, will now produce an enormous and divisive national uproar. Right in the middle of a presidential campaign. Good work, Massachusetts. ●



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# MATTERS OF THE HEART

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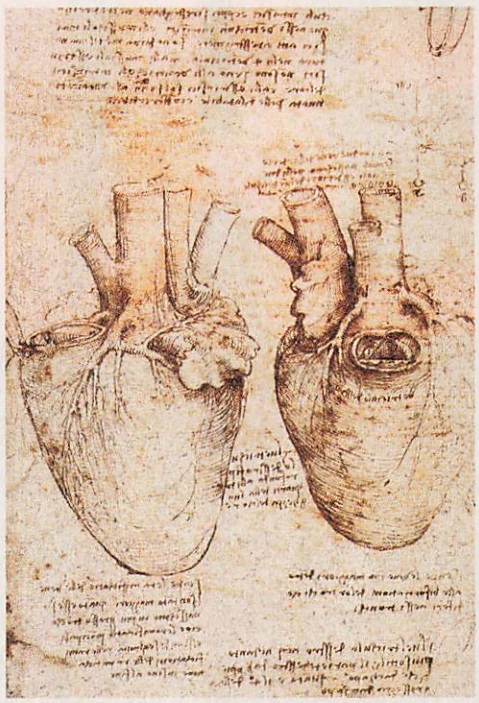
BY BERNADINE HEALY, M.D.

THE HEART HAS A MIND OF ITS OWN. It is prone to flutter in response to a kiss, skip a few beats in the klieg lights, brace itself in the face of treachery, and slow during slumber—except, of course, during a nasty dream. This ever vigilant organ sustains all others by pumping up to 6 gallons of blood per minute and propelling it through some 60,000 miles of tributaries to bathe, nourish, and cleanse virtually every cell in the body. A beating heart is the joyous first sign of life, and it's the sad final thump that marks the moment of death. In today's secular times, the heart has lost much of its cachet as the mansion of the soul, but it has not lost its romantic and spiritual grip on us. We all still speak of happy hearts, good hearts, heavy hearts, and brave hearts. We have all felt heartache and have even been heartsick. We've suffered when our heart's desires were not fulfilled and been bewildered by those who are heartless. Our own hearts rally for the lionhearted and yearn with the Tin Man in his desperation for a heart. We see wellness in the heartland and know instinctively that home is where the heart is.

Romance aside, there is in reality no other organ that works so hard and faithfully yet is taken so for granted. But reality has a darker side as well. The sick heart can afflict the body with profound fatigue, crushing chest pain, dizzying rhythms, and frightening breathlessness. That is the heart that the cardiologist knows, and all too well.

Cardiology is an aged medical specialty, tracing its scientific origins back to 1628 and the epochal discoveries of the British physician William Harvey. This reputed father of cardiology is credited with bringing medicine from the Dark Ages into the light of science and inquiry. His major work, *De Motu Cordis,* arrived around the same time that Galileo was being persecuted for his heretical view that the Earth was not the center of the universe. Harvey faired better, since his radical thought—that the heart was the all-powerful center in a circular motion of blood—appealed to the clerics of the day.

It's fortunate he was "politically correct" because he was keenly accurate. He overturned the encrusted belief that blood originated in the liver, drew spirit from the heart, and merely sloshed to and fro in its vessels. Studying living animals and human corpses, he spoke the obvious: Arteries carried blood away from the heart, veins brought the blood back, under the command of the contracting heart, which orchestrated rhythm and powered a ceaseless, closed-loop circulation of blood. For Harvey the heart was a sovereign "internal creature" that nourished and preserved the body throughout life. What he didn't imagine was just how high maintenance this sovereign creature could be.



**Da Vinci had an artistic appreciation of the heart.**

The heart has not lost its romantic and spiritual grip on us.

**Curiosity and technology.** The heart hid its tribulations well. It took a steady stream of technology to pry open its secrets in both sickness and health. For years physicians had been guided only by their bedside observations and an occasional epiphany from a stone-cold dissected heart. The stethoscope changed that, and that was sheer accident. In 1816, faced with the impropriety of listening to a young woman's chest by placing his ear on her bosom, French physician René Laënnec devised a long thin tube to distance himself from the damsel. In the process he and others learned that this bit of manners actually amplified sound. Suddenly, doctors could listen to the rhythms of the heart and the opening and closing of heart valves. They could detect murmurs and hear crackles from the lungs that signaled early heart failure. By detecting valve disease, doctors came to understand its perilous relationship to cardiac enlargement and failure. Bigger biceps are strong, but bigger hearts are weak.

Valve problems became the face of 19th-century heart disease. Streptococcal infection was common and triggered rheumatic fever, which in turn caused grotesque valve malformations with thickening of the heart's walls and enlargement of its chambers. Cardiac syphilis caused huge calcified aortic aneurysms at the root of the heart and damaged the attached aortic valves. It was the stethoscope that picked up these previously unrecognized problems and set the stage for the focused pursuit of solutions. Indeed, penicillin



THE GRANGER COLLECTION

in the next century would virtually wipe out both these diseases. In a recurrent cycle of seek and find, the stethoscope led to the external blood pressure cuff in 1905, which unveiled chronic hypertension, catalyzing a century of curative drug discovery.

Figuring out coronary artery disease, the biggest killer of men and women in modern times, has been slower going. In bygone years, chest pain was blamed on pneumonia or indigestion, and sudden death was an inexplicable, almost biblical event. One of the first hints that angina, sudden death, and coronary disease were linked came in 1793. John Hunter, a prominent surgeon troubled with bouts of chest pain, walked out of a hostile board meeting at St. George's Hospital, London, stifling his anger, and proceeded to groan and fall over dead in front of his colleagues (perhaps a prescient tale of a Type A personality). His renowned doctor, the discoverer of the pox vaccine, Edward Jenner, studied his autopsy, found "ossified" coronary arteries, and reasoned that they had caused the fatal weakness in his agitated heart.

To make sense of Hunter's storied demise, the Scottish anatomist Allan Burns designed a clever experiment, which he reported in 1809. It's still a neat trick for teaching medical students about alien concepts like "angina" and "ischemia." Recognizing that the heart was after all a muscle, he placed a tight tourniquet around the upper arm and then exercised the limb. In no time, profound fatigue and sickening pain set in and the arm falls immobile. Upon release of the tie, pain disappears and the muscle regains its life. Burns likened this to a stressed heart falling prey to narrowed arteries. Future generations of researchers confirmed his thinking, as did the 1903 Nobel Prize–winning discovery of the electrocardiogram by the Dutch scientist Willem Einthoven. With the EKG, doctors could detect ischemic heart muscle by changes in the electrical currents running through the injured part of the heart. EKGs also detected heart attacks, rhythm disorders, and the ventricular fibrillation of sudden cardiac death.

Another revolution was taking place about the same time in the autopsy room. Pathologists examining "ossified" coronary arteries found that they were actually plugged with fat-laden plaque. This suggested that these atheromas, as they were then called, came from cholesterol in the bloodstream or the diet. James Herrick of Rush University in Chicago discovered in 1912 that in heart attacks fresh blood clots had formed in arteries already narrowed by atheroma, pointing to the importance of the clotting system in this disease. The current "new" and popular culprit of coronary obstruction, inflammation, was actually suggested by these early pathologists. They observed that inflammatory cells were inveterate companions of the fatty plaques and seemed likely accomplices.

The one technology that most catapulted knowledge of the living heart was cardiac catheterization. The notion that one could touch the beating heart without peril was unthinkable in 1929. But Berlin's Werner Forssmann, fresh out of medical school, felt otherwise. When his professor dismissed his pipe dreams, Forssmann catheterized himself by threading a bladder catheter through an artery in his left arm into his heart. Catheter in place, he walked to radiology for a chest X-ray, the in-your-face proof that he had both succeeded and survived. His continued self-experimentation brought him more ridicule than recognition. Such boldness fared better in New York City, where 10 years later André Cournand and Dickinson Richards began catheterizing heart patients. This won all three physicians the Nobel Prize and, more important, changed cardiovascular medicine forever.

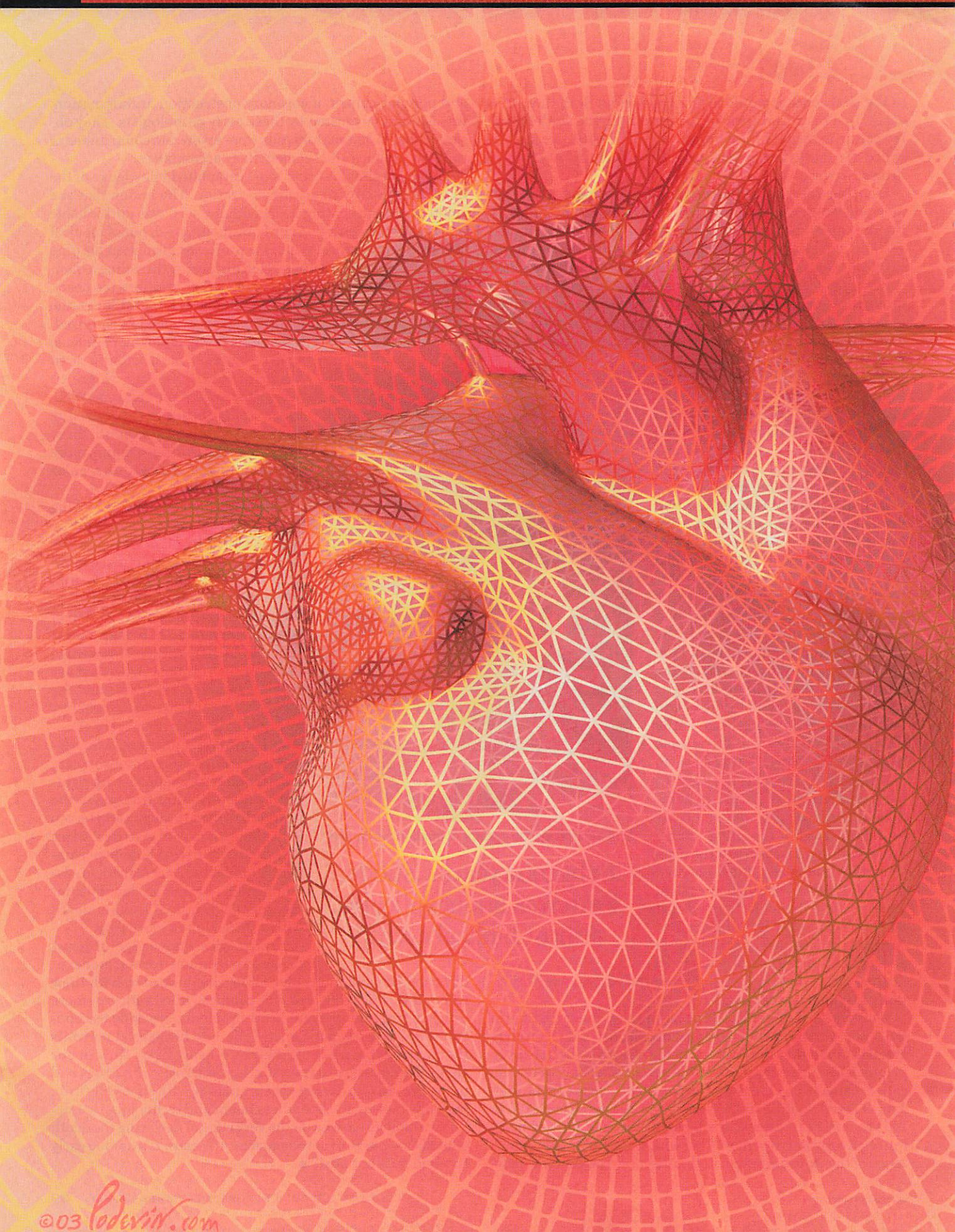
**William Harvey, the creator of modern cardiology**

"In bygone years... sudden death was an inexplicable, almost biblical event."

Catheterization became the looking glass and the portal for mending hearts. When in 1958 Mason Sones of the Cleveland Clinic discovered how to slip catheters directly into coronary arteries in motion and inject them with dye, the ability to detect coronary atheromas in living patients suddenly became reality. This opened the door for coronary artery bypass surgery and then, 20 years later, for coronary angioplasty, using catheters and stents instead of surgery to restore blood flow. Catheterization triggered other lifesavers. Intensive care units monitor sick patients with right-heart catheters. After transplant, the heart is biopsied through catheters to detect rejection. And electrical wires threaded into hearts enable permanently implanted pacemakers to sustain rhythm—or wait on standby to interrupt the drama of sudden death with a stored jolt of electricity.

Armed with knowledge of heart disease in its many forms, modern-day chemists and molecular biologists jumped in with their technologies. Bulging medicine cabinets, filled with ever more drugs to treat and prevent heart problems, are daily testimony to this, as are genetic, metabolic, and behavioral portraits that help people ward off their own heart risks. Now in our sights are therapies to reverse atherosclerosis with drugs and to restore vigor to damaged heart muscle with stem cells from marrow. Indeed, the boundless talent and technology that define cardiology have us on the very edge of declaring the death of today's scourge of coronary artery disease. It's not too early to wonder, What next? ●

MARY EVANS PICTURE LIBRARY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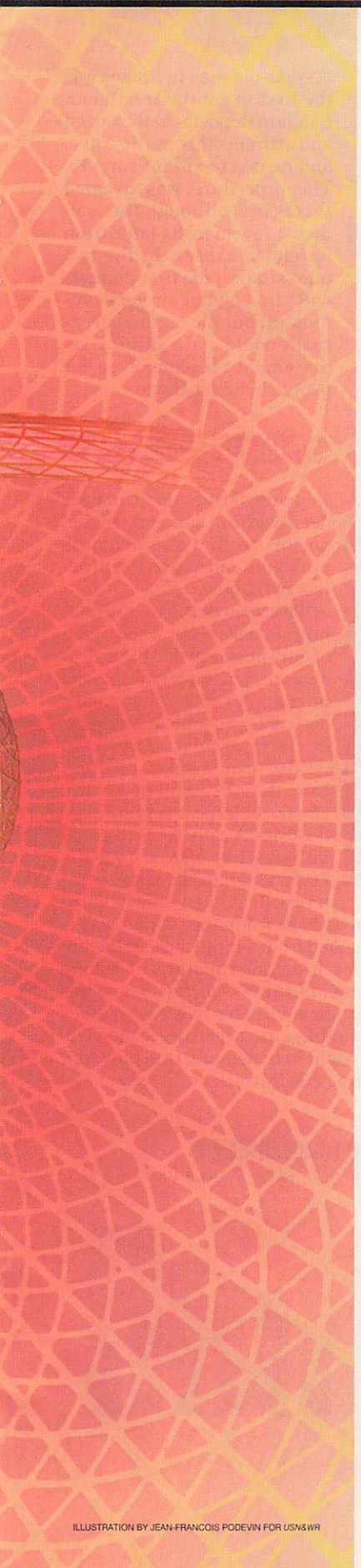


Stem cells, plaque detectors, and superpowered 'good cholesterol' are changing the odds against a killer

# THE FUTURE IS NOW

By Avery Comarow and Bernadine Healy, M.D.

This is an electric moment for heart researchers. Decades of painstaking lab work, clinical studies, technological advances, and insights into the heart's special biology are yielding a cornucopia of important drugs and devices, even therapies in which replacement cells and parts come from the patient's own body. The pace of discovery is astonishing. If an increasingly obese and exercise-phobic nation will decide to change its ways enough to give these developments a foothold, the toll exacted by coronary artery disease and other heart conditions could plummet in a few short years. "I've never been more optimistic," says Kim Eagle, clinical director of the University of Michigan cardiovascular center.

He's not alone. At last month's meeting of the American Heart Association, planners had to add an extra session showcasing significant late-breaking clinical trials of a wide variety of therapies. "There were just too many good ones to leave out," says program chairman Raymond Gibbons, a Mayo Clinic cardiologist. And that was just a small sample of developments in this field. All over the world, basic scientists, clinicians—and thousands of patients in important clinical trials—are changing the face of cardiovascular medicine. The following rundown of some of the powerful discoveries, almost all of which have moved beyond the research laboratory to patients in need,

ILLUSTRATION BY JEAN-FRANCOIS PODEVIN FOR *USN&WR*

illustrates why specialists are so hopeful—and why patients can hope, too.

## BREAKTHROUGH DRUGS

No one seriously disagrees that when it comes to LDL, the bad cholesterol, lower is better. But pharmaceutical manufacturers are looking at ways to diminish heart risk that do more than push down the LDL number.

**HDL boosters.** Statin drugs dramatically lower LDL but barely improve HDL, the good kind. Last month came news of a synthetic form of HDL that can shrink fat-laden deposits in the coronary arteries in a mere five weeks. The drug, given intravenously, looked promising in a test of several dozen patients. Raising HDL or making it more effective is the idea behind many current drug trials, because HDL clears cholesterol out of artery walls and carries it back to the liver. In another study, an HDL-raising drug was delivered as a vaccine that stimulates the immune system to block CETP, a protein involved in cholesterol transfer.

**Reblockage blockers.** Most of the time after a blocked coronary artery is reopened, a metal mesh cylinder called a stent is put in place to hold it open (Page 58). The vessel frequently recloses within six months or so, however, when tissue grows into the stent. New drug-coated stents are an increasingly popular response to the problem, but they're expensive. Cilostazol, a drug prescribed for leg pain, was found in a just concluded study to sharply reduce reblockages.

## REPAIRS THROUGH A TUBE

If you needed a heart operation and could have it done with (a) conventional surgery that opens up your chest or (b) through a small tube inserted into a tiny incision and pushed up to your heart, which would you choose? Small tubes and tiny cuts sound much better, of course. That's why interventional cardiology, which uses the tubes, is so hot—and heart surgeons are getting nervous.

**Zapping a bad beat.** The heart is an electrical organ, its beat coordinated by impulses that move across the heart in synchronized rhythm—most of the time. An estimated 2 million Americans suffer from atrial fibrillation: The two upper chambers beat irregularly and rapidly, up to 175 times a minute, causing palpitations and, in severe cases, shortness of breath and other symptoms. Last month, a University of Michigan team revealed a new, remarkably effective way to cure atrial fibrillation. They pushed one of those little tubes, or catheters, into the heart and zapped the inside of the left atrium in precisely calculated spots with a little electrical jolt. After six months, 88 percent of the patients who got the procedure were completely cured.

**Valve replacement.** Two pilot studies, one recently begun in Europe, the other soon to get underway in the United States, will evaluate a technique for implanting an artificial heart valve without surgery. Collapsed into a cigar shape just a fraction of an inch wide, the valve is passed through a tube into the heart and wedged into place by inflating a balloon behind it. Last year, a 57-year-old man in France was the first to get the treatment. Calcium deposits had clogged and stiffened his aortic valve, and he was too ill for surgery. The procedure was deemed successful, although the man died a few months later from unrelated causes. In the two pilot studies, the first patients will also be poor surgery candidates, but the method eventually could make surgical replacement obsolete, even for people in better shape.

### A YEAR'S TOLL

*Causes of cardiovascular deaths in 2001*

0.4% RHEUMATIC FEVER AND HEART DISEASE
0.5% CONGENITAL DEFECTS
4% DISEASES OF ARTERIES
5% HIGH BLOOD PRESSURE
6% HEART FAILURE
12% OTHER CARDIOVASCULAR DISEASE
18% STROKE
54% CORONARY ARTERY DISEASE
Note: Numbers do not add up to 100 percent because of rounding.
Source: Centers for Disease Control and Prevention

## INSIGHTFUL TECHNOLOGIES

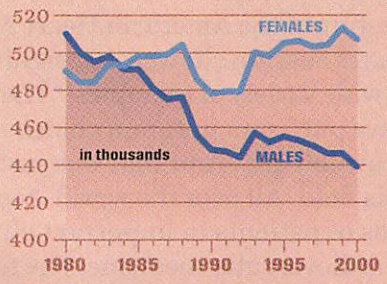
Imaging devices that can peer deep within the heart enable doctors to find and diagnose problems and assess the progress of therapy.

**Ultrasonic view.** Two thirds of heart attacks occur when a glob of fatty plaque inside the wall of a coronary artery bursts into the interior. But doctors have never been able to see plaques directly. Intravascular ultrasound (IVUS) can display plaques, from their beginnings as fatty streaks to large, ready-to-blow deposits. A catheter is inserted into an artery, moved up to the heart, and into the vessel of interest. It is then slowly withdrawn as high-frequency sound waves are beamed from a transducer at the tip, painting a detailed picture of a long stretch of blood vessel. Trials now underway should be able to verify whether IVUS findings are accurate. If they are, IVUS could help demonstrate how well new drugs really work by directly show-

USN&WR (2)

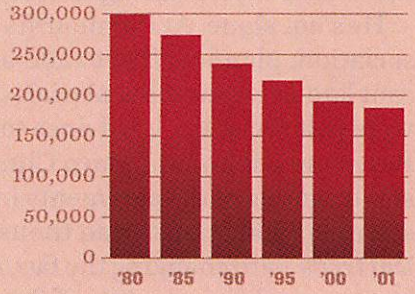
### SEX AND DEATH

*A gender gap in cardiovascular deaths*



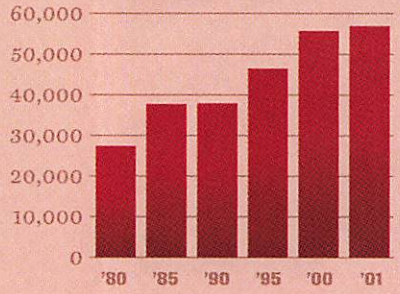

### ATTACKS ARE DOWN...

*Annual deaths from heart attacks*




### ...BUT FAILURES ARE UP

*Annual deaths from heart failure*




Sources: American Heart Association, Centers for Disease Control and Prevention

# THIS TEST COULD HELP SAVE YOUR LIFE.

- ☐ MAN OVER 40
- ☐ WOMAN OVER 50
- ☐ HIGH CHOLESTEROL
- ☐ FAMILY HISTORY OF HEART DISEASE

If you checked one or more of these boxes, you may be at a greater risk of a heart attack.

Take this test to your doctor,* and ask if Bayer® could help save your life.

You may be surprised to find you could be at a greater risk of a heart attack than you think. And doctors will often recommend Bayer, the leading low-dose aspirin brand. Studies show regular use of aspirin can prevent nearly one out of three heart attacks.

Aspirin is not appropriate for everyone, so be sure to talk to your doctor before you begin an aspirin regimen.

## TRUST YOUR HEART TO BAYER.

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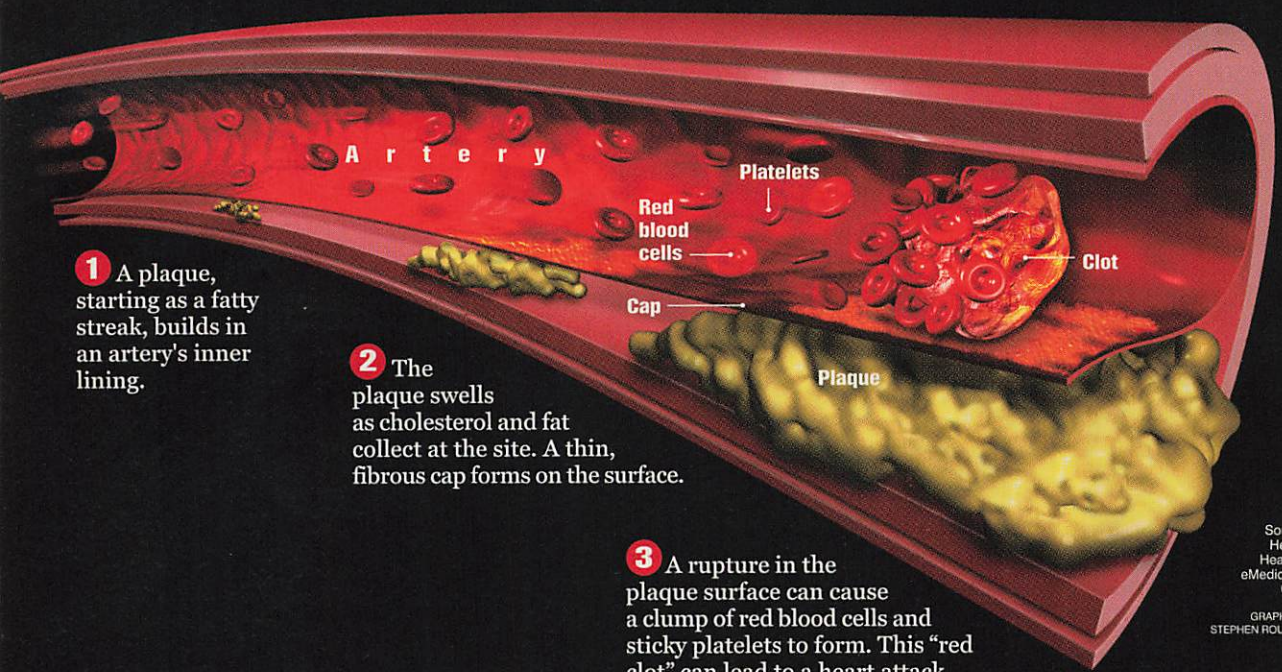
*Be sure to discuss all of your risk factors with your doctor.

# THE PULSE OF LIFE–AND DEATH

*It's the one organ that keeps the rest of you going, pumping oxygen-rich blood to every other body part. But the heart has a delicate, elegant anatomy, and when it breaks down havoc breaks loose.*

## BULGES AND CLOTS

Blood flow is prone to a problem called atherosclerosis. Arteries that supply blood can become narrowed as plaques grow within their walls, forming out of cholesterol, fatty compounds, calcium, and a tough, fibrous material. These plaques lead to clots, dangerously irregular heartbeats, and heart attacks.




**1** A plaque, starting as a fatty streak, builds in an artery's inner lining.

**2** The plaque swells as cholesterol and fat collect at the site. A thin, fibrous cap forms on the surface.

**3** A rupture in the plaque surface can cause a clump of red blood cells and sticky platelets to form. This "red clot" can lead to a heart attack.

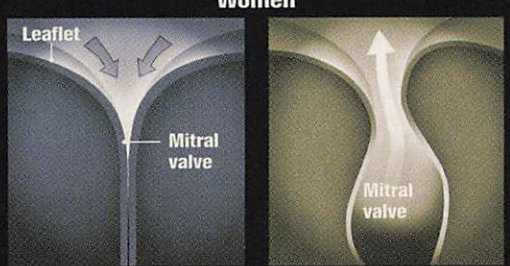
Sources: American Heart Association; HeartCenter Online; eMedicine.com; James Chen-Tson Fang

GRAPHIC BY ROD LITTLE, STEPHEN ROUNTREE AND DOUG STERN—*USN&WR*

## WHEN GOOD VALVES GO BAD

Valves control the flow of blood through the heart. Women seem to have more defects in the mitral valve, while men have more defects in the aortic valve.

**Women**



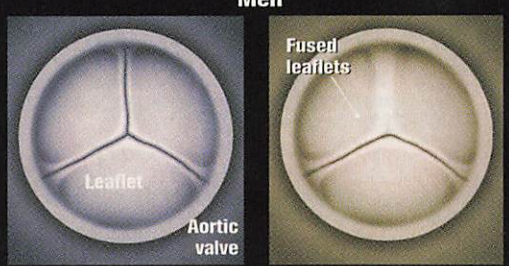

**Healthy**

The mitral valve has two leaflets—flaps that allow oxygen-rich blood to pass from the left atrium to the left ventricle, and close to prevent it from flowing back.

**Floppy**

Sometimes the flaps don't close evenly, allowing a backflow of blood. If the flow is large, it can cause enlargement or thickening of the heart muscle.

**Men**

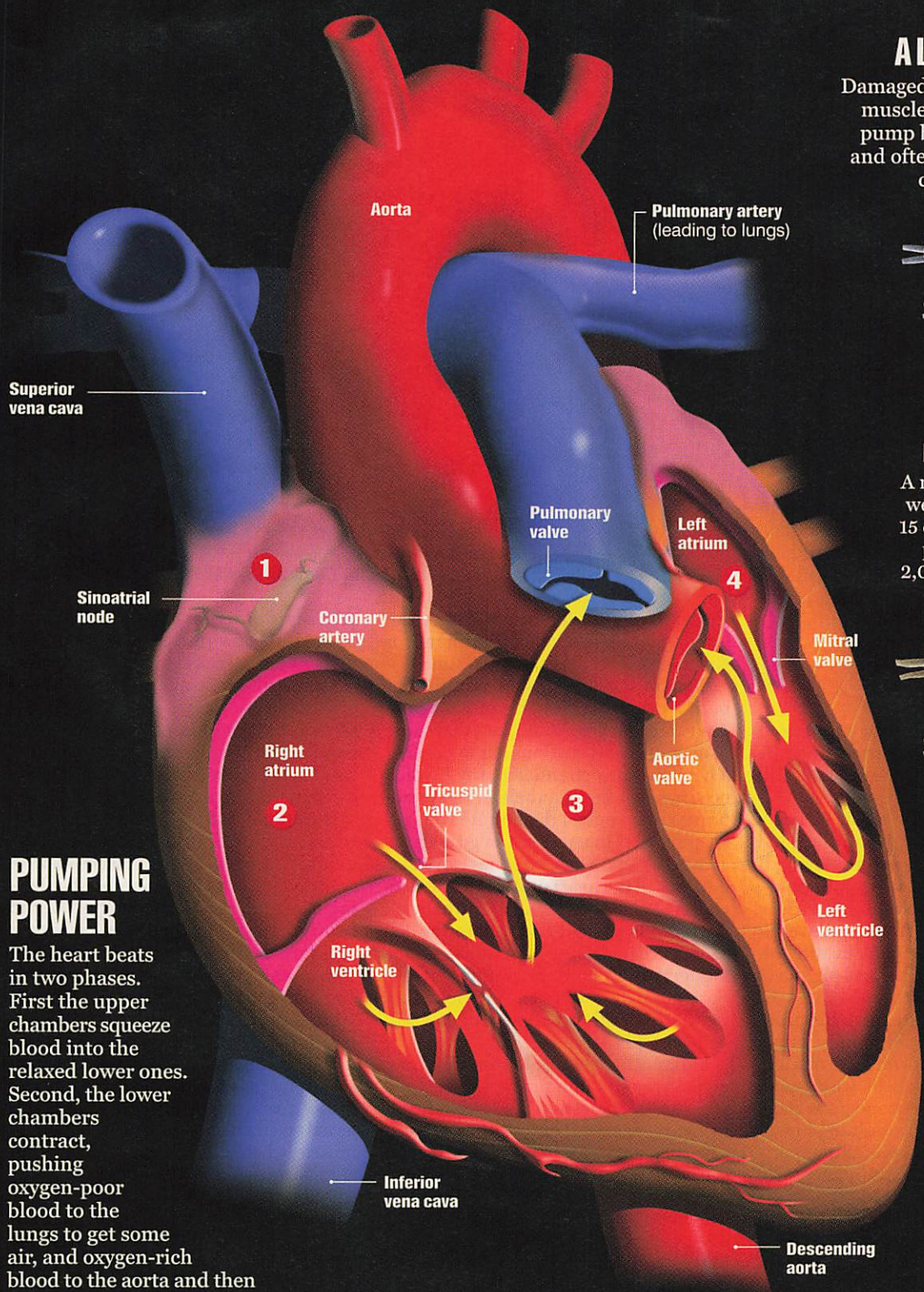



**Healthy**

The aortic valve, with three leaflets, opens so the left ventricle can shoot blood into the aorta and then to the rest of the body.

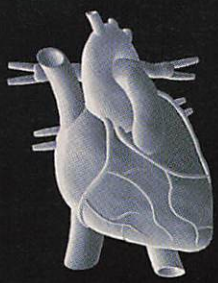
**Fused**

Sometimes two of the leaflets are fused together, a congenital defect. This can lead to a narrowed opening or backflow through the valve.



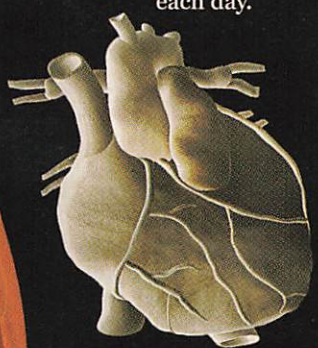

## A LOSING BATTLE

Damaged, overworked heart muscle loses the ability to pump blood, an incurable and often deadly condition called heart failure.



### Healthy muscle

A normal heart, which weighs between 7 and 15 ounces, is capable of pumping more than 2,000 gallons of blood each day.



### Failure

In end-stage heart failure, the heart has exhausted itself, and sagging, swollen muscles have quadrupled the organ's size. Bigger is not better: The weakened muscle can no longer pump out enough blood.

## PUMPING POWER

The heart beats in two phases. First the upper chambers squeeze blood into the relaxed lower ones. Second, the lower chambers contract, pushing oxygen-poor blood to the lungs to get some air, and oxygen-rich blood to the aorta and then on to the rest of the body.

**1** The sinoatrial node, the heart's "pacemaker," sends an electrical signal causing the upper chambers, or atria to contract.

**2** Deoxygenated blood flows from the right atrium to the right ventricle.

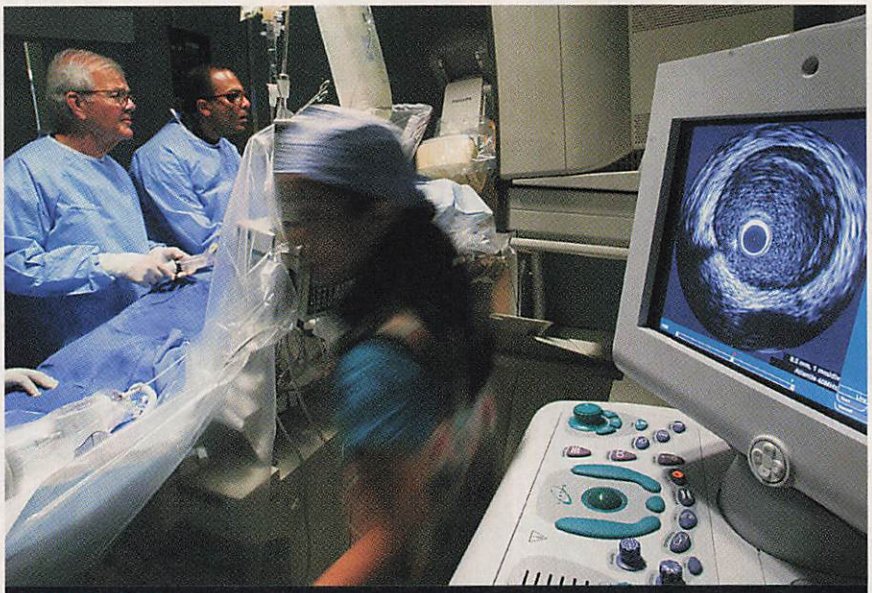
**3** The right ventricle contracts, sending blood toward the lungs to pick up oxygen.

**4** Oxygenated blood returns to the left atrium and then to the left ventricle, which pumps it back to the rest of the body.

ing whether they have an effect inside artery walls, where it counts. That could speed up the time it takes new drugs to get approved for use.

**New CT scanners.** The latest version, 16-slice CT, has some of IVUS's ability to look inside blood-vessel walls—and unlike IVUS, a CT scan can be done without threading a catheter into the body and up to the heart. Potential problem? CT scanners use X-rays, and some physicians worry about adding to the radiation dose patients receive now.

**Echoes from the heart.** Stethoscopes are convenient but limited; a suspicious sound can indicate more than one problem. Portable versions of Doppler echocardiography devices have been developed that could replace the stethoscope. "Doppler echo" uses high-frequency sound waves to generate images of features like faulty valves and aortic aneurysms. With a hand-held version, a wand passed over parts of the body could detect problems. A currently available model costs about $12,000, but prices are expected to fall below $1,000.



**INSIDE VIEW.** Doctors at the Washington Hospital Center use intravascular ultrasound to see inside blood vessel walls and search for deadly plaques.

## SURGICAL ADVANCES

Surgery may be down—the number of coronary-artery-bypass procedures is drifting downward—but surgeons still have a trick or two up their gloves.

**Growing a new heart valve.** Fixing a badly diseased aortic valve surgically is done by cutting it out and replacing it with the individual's own pulmonary valve—which in turn is replaced with an artificial valve or one from a cadaver or pig. But there aren't enough healthy cadaver valves, and artificial and pig valves tend to fail early when used in this way. German doctors sidestepped this problem by creating new pulmonary valves for 23 patients with aortic valve disease. The researchers took cells from small pieces of leg or arm vein and grew them into valve flaps on a scaffolding of collagen, a protein that shapes and supports tissue. After three years, the homegrown valves reportedly are trouble free.

## THE GENETIC PATHWAY

Heart disease gets personal when your doctor starts bringing family history into the discussion. But history is influenced by genes, and genetics is about to become a powerful weapon. Once genes are identified for specific diseases, targets for diagnosis and treatment become clearer. In the not-too-distant future, tailored, gene-based heart treatment for you and your family will be routine.

**Rhythm and blues.** Some families inherit a predisposition to sudden death. The search for gene mutations that cause dangerous heart rhythms has uncovered a new disease, "channelopathy," which occurs when the channels in cell membranes that control the minute voltages keeping cells in equilibrium go awry.

**Heart failure.** Mutated genes can cause diseases of the heart muscle that lead to end-stage heart failure. For virtually all the mutations identified to date, the disorders are in proteins that make up the "squeezing" filaments of muscle cells. For a given disorder, some mutations are riskier than others. Gene analysis will help sort all that out.

**Different coronaries.** In some families, genes are to blame for sky-high blood pressure or cholesterol levels that result in heart disease. Now studies are uncovering molecules in the arteries themselves that raise risk levels. One of them is tied to coronary spasm and chest pain. This week, researchers announced the discovery of a "heart attack gene" that makes cells in artery walls especially prone to atherosclerosis.

## DEPLOYING STEM CELLS

"End-stage heart disease" is a grim diagnosis with few good options. But if your stem cells, which can turn themselves into different mature cells, can be coaxed to grow into new heart tissue, there's hope. Because this doesn't involve cells from other people's embryos, there are no rejection risks—or ethical roadblocks. Last month, promising results from several studies, involving over 100 people, hint that a breakthrough therapy is on the verge of becoming real.

**Muscle progenitors.** Stem cells harvested and grown from a bit of thigh muscle—a close cousin to cardiac muscle—can be delivered directly into an injured or failing heart. The cells become part of the heart, though it's still unclear whether they turn "cardiac" and if so for how long.

**Bone marrow stem cells.** Heart muscle can also be infused with stem cells extracted from bone marrow, but that extraction is painful. Yet with the help of G-CSF, a drug that stimulates bone marrow, millions of such cells pour into the bloodstream, where they can be easily collected and then injected directly into heart muscle, where they appear to morph into cardiac muscle and blood vessels.

**Calling all cells.** Scientists have discovered "homing factors" that summon stem cells to a wounded heart. But in the normal course of events, such substances are produced only briefly after a heart attack. If the homing factors bear out, they can be combined with G-CSF's ability to rev up the stem-cell population so the cells can be delivered naturally, over a long period of time. ●

*With Helen Fields*



JEFFREY MACMILLAN FOR *USN&WR*

# WHAT ARE YOU DOING TO HELP PROTECT YOUR HEART?

You do all kinds of things to help safeguard yourself. And yet, if you've had a heart attack or stroke, it's important to ask your doctor if you're doing enough to help protect your heart. The Heart Protection Study by Oxford University, funded in part by Merck, researched ZOCOR.

ZOCOR is the first and only cholesterol medication proven to significantly reduce the risk of heart attack and stroke in people with heart disease. Regardless of cholesterol level.

Before the Heart Protection Study was complete, ZOCOR was a time-tested, cholesterol-lowering medication, with over 160 million prescriptions filled in the past 11 years.

Ask your doctor how ZOCOR, along with a healthy diet, can help protect you. Get information about the Heart Protection Study and ZOCOR at ***zocor.com*** or call 1-800-MERCK-75.

INFORMATION ABOUT THE HEART PROTECTION STUDY AND ZOCOR® (SIMVASTATIN)

ZOCOR® (SIMVASTATIN)

**Important considerations:** ZOCOR is a prescription medicine and isn't right for everyone, including women who are nursing or pregnant or who may become pregnant, anyone with liver problems, and people who are allergic to any ingredients of ZOCOR. Unexplained muscle pain or weakness could be a sign of a rare but serious side effect and should be reported to your doctor right away. Your doctor may do blood tests before and during treatment with ZOCOR to check for liver problems. To avoid serious side effects, discuss with your doctor medicine or food you should avoid while on ZOCOR.

YOUR RESULTS MAY VARY.

PLEASE READ THE MORE DETAILED INFORMATION ABOUT ZOCOR IMMEDIATELY FOLLOWING THIS AD.

ASK YOUR DOCTOR IF ZOCOR IS RIGHT FOR YOU.

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**ZOCOR. It's your future. Be there.**

# ZOCOR®
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**PLEASE READ THIS SUMMARY CAREFULLY, THEN ASK YOUR DOCTOR ABOUT ZOCOR. NO ADVERTISEMENT CAN PROVIDE ALL THE INFORMATION NEEDED TO PRESCRIBE A DRUG. THIS ADVERTISEMENT DOES NOT TAKE THE PLACE OF CAREFUL DISCUSSIONS WITH YOUR DOCTOR. ONLY YOUR DOCTOR HAS THE TRAINING TO WEIGH THE RISKS AND BENEFITS OF A PRESCRIPTION DRUG FOR YOU.**

## USES OF ZOCOR

ZOCOR is a prescription drug that is indicated as an addition to diet for many patients with high cholesterol. For patients at high risk of coronary heart disease (CHD) because of existing heart disease, diabetes, vascular disease, or history of stroke, ZOCOR is indicated along with diet to reduce the risk of death by reducing coronary death; reduce the risk of heart attack and stroke; and reduce the need for revascularization procedures.

## WHEN ZOCOR SHOULD NOT BE USED

Some people should not take ZOCOR. Discuss this with your doctor.

ZOCOR should not be used by patients who are allergic to any of its ingredients. In addition to the active ingredient simvastatin, each tablet contains the following inactive ingredients: cellulose, lactose, magnesium stearate, iron oxides, talc, titanium dioxide, and starch. Butylated hydroxyanisole is added as a preservative.

**Patients with liver problems:** ZOCOR should not be used by patients with active liver disease or repeated blood test results indicating possible liver problems. (See WARNINGS.)

**Women who are or may become pregnant:** Pregnant women should not take ZOCOR because it may harm the fetus. **Women of childbearing age should not take ZOCOR unless it is highly unlikely that they will become pregnant.** If a woman does become pregnant while on ZOCOR, she should stop taking the drug and talk to her doctor at once.

**Women who are breast-feeding** should not take ZOCOR.

## WARNINGS

**Muscle: Tell your doctor right away if you experience any unexplained muscle pain, tenderness, or weakness at any time during treatment with ZOCOR so your doctor can decide if ZOCOR should be stopped. Some patients may have muscle pain or weakness while taking ZOCOR. Rarely, this can include muscle breakdown resulting in kidney damage. The risk of muscle breakdown is greater in patients taking certain other drugs along with ZOCOR:**

- **Cyclosporine, itraconazole, ketoconazole, erythromycin, clarithromycin, HIV protease inhibitors, the antidepressant nefazodone, or large quantities of grapefruit juice (>1 quart daily), particularly with higher doses of ZOCOR.**
- **Gemfibrozil, other fibrates, or lipid-lowering doses (≥1 g/day) of niacin, particularly with higher doses of ZOCOR.**
- **Amiodarone or verapamil with higher doses of ZOCOR.**

**The risk of muscle breakdown is greater at higher doses of simvastatin.**

**Because the risk of muscle side effects is greater when ZOCOR is used with the products listed above, the combined use of these products should be avoided unless your doctor determines the benefits are likely to outweigh the increased risks.**

**If your doctor determines that the benefits of combined use of ZOCOR with gemfibrozil, other fibrates, or niacin likely outweigh the increased risk of muscle problems, the dose of ZOCOR should not exceed 10 mg daily. No more than 10 mg/day of ZOCOR should be taken with cyclosporine.**

**The combined use of verapamil or amiodarone with doses above ZOCOR 20 mg should be avoided unless your doctor determines the benefits outweigh the increased risk of muscle breakdown.**

**Your doctor should also carefully monitor for any muscle pain, tenderness, or weakness, particularly during the initial months of therapy and if the dose of either drug is increased. Your doctor also may monitor the level of certain muscle enzymes in your body, but there is no assurance that such monitoring will prevent the occurrence of severe muscle disease.**

**The risk of muscle breakdown is greater in patients with kidney problems or diabetes.**

**If you have conditions that can increase your risk of muscle breakdown, which in turn can cause kidney damage, your doctor should temporarily withhold or stop ZOCOR. Also, since there are no known adverse consequences of briefly stopping therapy with ZOCOR, treatment should be stopped a few days before elective major surgery and when any major acute medical or surgical condition occurs. Discuss this with your doctor, who can explain these conditions to you.**

**Liver: About 1% of patients who took ZOCOR in clinical trials developed elevated levels of some liver enzymes.** Patients who had these increases usually had no symptoms. Elevated liver enzymes usually returned to normal levels when therapy with ZOCOR was stopped.

In the ZOCOR Survival Study, the number of patients with more than 1 liver enzyme level elevation to greater than 3 times the normal upper limit was no different between the ZOCOR and placebo groups. Only 8 patients on ZOCOR and 5 on placebo discontinued therapy due to elevated liver enzyme levels. Patients were started on 20 mg of ZOCOR, and one third had their dose raised to 40 mg.

**Your doctor should perform routine blood tests to check these enzymes before you start treatment with ZOCOR and thereafter when clinically indicated. Patients titrated to the 80-mg dose should receive an additional test at 3 months and periodically thereafter (eg, semiannually) for the first year of treatment.** If your enzyme levels increase, your doctor should order more frequent tests. If your liver enzyme levels remain unusually high, your doctor should discontinue your medication.

Tell your doctor about any liver disease you may have had in the past and about how much alcohol you consume. ZOCOR should be used with caution in patients who consume large amounts of alcohol.

## PRECAUTIONS

**Drug Interactions:** Because of possible serious drug interactions, it is important to tell your doctor what other drugs you are taking, including those obtained without a prescription. You should also tell other doctors who are prescribing a new medicine for you that you are taking ZOCOR. ZOCOR can interact with the following:

- Itraconazole
- Ketoconazole
- Erythromycin
- Clarithromycin
- HIV protease inhibitors
- Nefazodone
- Cyclosporine
- Large quantities of grapefruit juice (>1 quart daily)

The risk of myopathy is also increased by the following lipid-lowering drugs that can cause myopathy when given alone:

- Gemfibrozil
- Other fibrates
- Niacin (nicotinic acid) (≥1 g/day)

The risk of muscle breakdown is increased with other drugs:

- Amiodarone
- Verapamil

Some patients taking lipid-lowering agents similar to ZOCOR® (simvastatin) and coumarin anticoagulants (a type of blood thinner) have experienced bleeding and/or increased blood clotting time. Patients taking these medicines should have their blood tested before starting therapy with ZOCOR and should continue to be monitored.

**Central Nervous System Toxicity; Cancer, Mutations, Impairment of Fertility:** Like most prescription drugs, ZOCOR was required to be tested on animals before it was marketed for human use. Often these tests were designed to achieve higher drug concentrations than humans achieve at recommended dosing. In some tests, the animals had damage to the nerves in the central nervous system. In studies of mice with high doses of ZOCOR, the likelihood of certain types of cancerous tumors increased. No evidence of mutations of or damage to genetic material has been seen. In 1 study with ZOCOR, there was decreased fertility in male rats.

**Pregnancy:** Pregnant women should not take ZOCOR because it may harm the fetus.

Safety in pregnancy has not been established. In studies with lipid-lowering agents similar to ZOCOR, there have been rare reports of birth defects of the skeleton and digestive system. Therefore, women of childbearing age should not take ZOCOR unless it is highly unlikely they will become pregnant. If a woman does become pregnant while taking ZOCOR, she should stop taking the drug and talk to her doctor at once. The active ingredient of ZOCOR did not cause birth defects in rats at 3 times the human dose or in rabbits at 3 times the human dose.

**Nursing Mothers:** Drugs taken by nursing mothers may be present in their breast milk. Because of the potential for serious adverse reactions in nursing infants, a woman taking ZOCOR should not breast-feed. (See WHEN ZOCOR SHOULD NOT BE USED.)

**Pediatric Use:** ZOCOR is not recommended for children or patients under 10 years of age.

**Geriatric Use:** Higher blood levels of active drug were seen in elderly patients (70–78 years of age) compared with younger patients (18–30 years of age) in 1 study. In other studies, the cholesterol-lowering effects of ZOCOR were at least as great in elderly patients as in younger patients, and there were no overall differences in safety between elderly and younger patients over the 20–80 mg/day dosage range. Of the 7 cases of myopathy/rhabdomyolysis among 10,269 patients on ZOCOR in another study, 4 were aged 65 or more (at baseline), 1 of whom was over 75.

## SIDE EFFECTS

Most patients tolerate treatment with ZOCOR well; however, like all prescription drugs, ZOCOR can cause side effects, and some of them can be serious. Side effects that do occur are usually mild and short-lived. Only your doctor can weigh the risks versus the benefits of any prescription drug. In clinical studies with ZOCOR, less than 1.5% of patients dropped out of the studies because of side effects. In 2 large, 5-year studies, patients taking ZOCOR experienced similar side effects to those patients taking placebo (sugar pills). Some of the side effects that have been reported with ZOCOR or related drugs are listed below. This list is not complete. Be sure to ask your doctor about side effects before taking ZOCOR and to discuss any side effects that occur.

**Digestive System:** Constipation, diarrhea, upset stomach, gas, heartburn, stomach pain/cramps, anorexia, loss of appetite, nausea, inflammation of the pancreas, hepatitis, jaundice, fatty changes in the liver, and, rarely, severe liver damage and failure, cirrhosis, and liver cancer.

**Muscle, Skeletal:** Muscle cramps, aches, pain, and weakness; joint pain; muscle breakdown.

**Nervous System:** Dizziness, headache, insomnia, tingling, memory loss, damage to nerves causing weakness and/or loss of sensation and/or abnormal sensations, anxiety, depression, tremor, loss of balance, psychic disturbances.

**Skin:** Rash, itching, hair loss, dryness, nodules, discoloration.

**Eye/Senses:** Blurred vision, altered taste sensation, progression of cataracts, eye muscle weakness.

**Hypersensitivity (Allergic) Reactions:** On rare occasions, a wide variety of symptoms have been reported to occur either alone or together in groups (referred to as a syndrome) that appeared to be based on allergic-type reactions, which may rarely be fatal. These have included 1 or more of the following: a severe generalized reaction that may include shortness of breath, wheezing, digestive symptoms, and low blood pressure and even shock; an allergic reaction with swelling of the face, lips, tongue, and/or throat with difficulty swallowing or breathing; symptoms mimicking lupus (a disorder in which a person's immune system may attack parts of his or her own body); severe muscle and blood vessel inflammation, sometimes including rash; bruises; various disorders of blood cells (that could result in anemia, infection, or blood clotting problems) or abnormal blood tests; inflamed or painful joints; hives; fatigue and weakness; sensitivity to sunlight; fever, chills; flushing; difficulty breathing; and severe skin disorders that vary from rash to a serious burn-like shedding of skin all over the body, including mucous membranes such as the lining of the mouth.

**Other:** Loss of sexual desire, breast enlargement, impotence.

**Laboratory Tests:** Liver function test abnormalities including elevated alkaline phosphatase and bilirubin; thyroid function abnormalities.

**NOTE: This summary provides important information about ZOCOR. If you would like more information, ask your doctor or pharmacist to let you read the prescribing information and then discuss it with them.**

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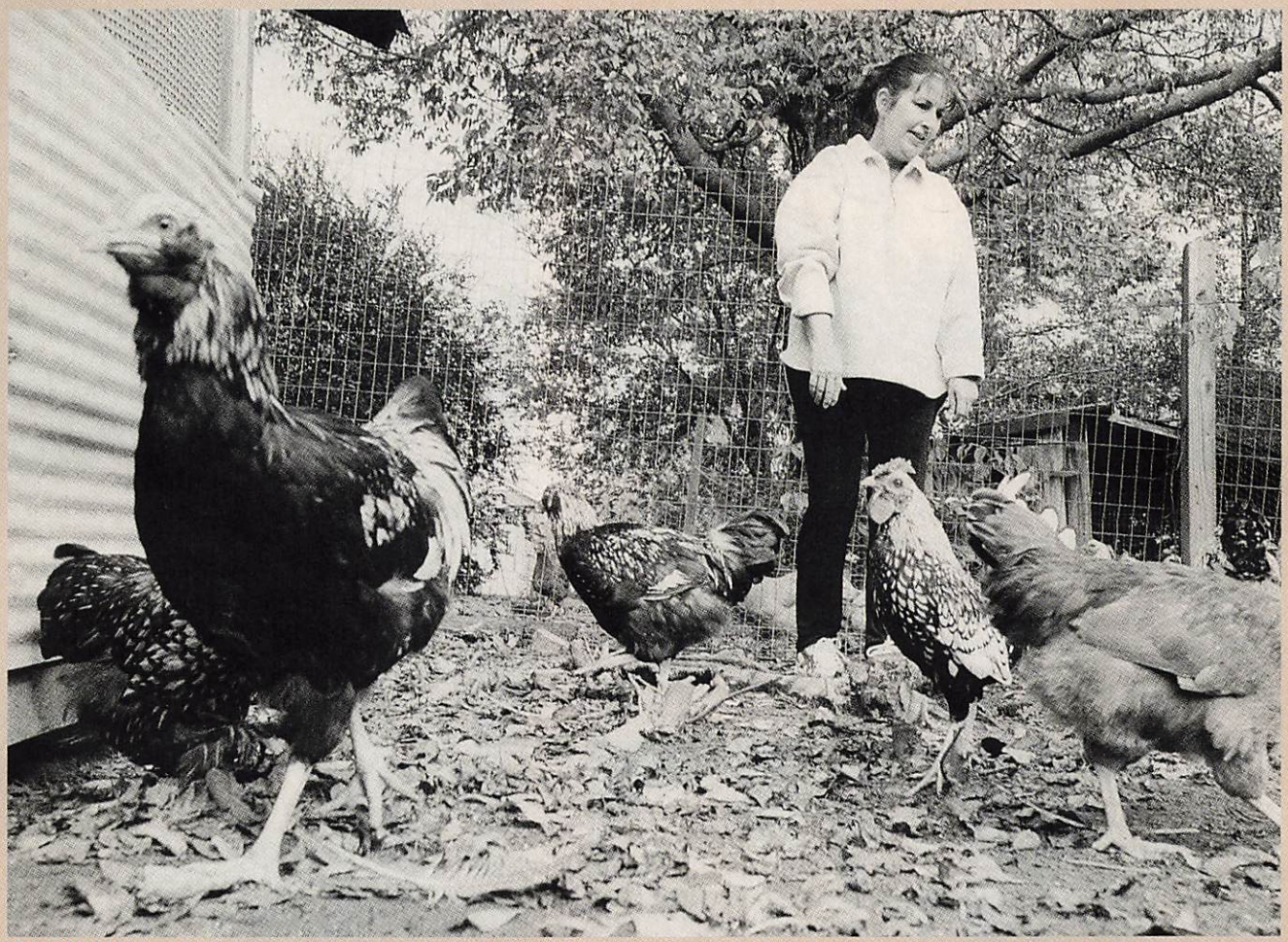


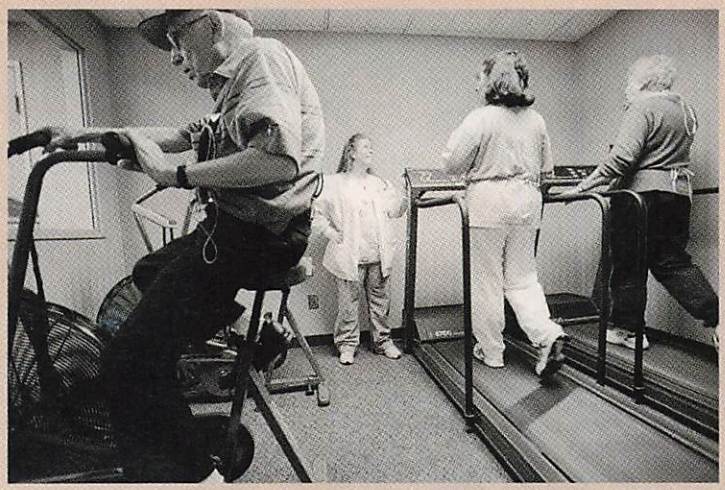
**ALL'S WELL.** For Tami Speers, stress relief comes from tending chickens. "They don't require anything except a little feed."

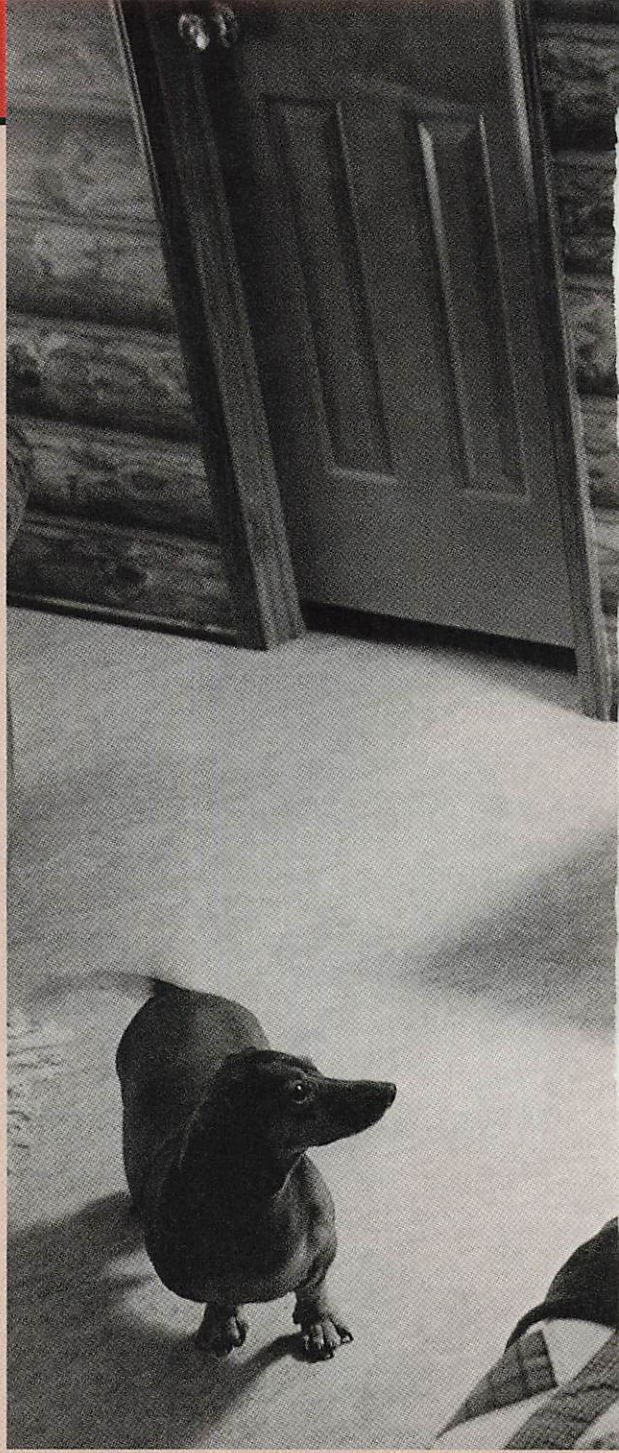
# A DAY AT A TIME

BY SUSAN BRINK

When Tami Speers feels anxious or stressed out these days, she ambles out to her backyard and sits with the chickens. The roosters strut, the hens cluck, and in the spring, the chicks are as cute as fuzzy buttons. It's all so natural, so predictable, so easy on the nerves. This placid scene is a far cry from her frenetic life before July 17, 2000, when she suffered a massive heart attack at the age of 40.

For 20 years, Speers had been a program manager for an aircraft manufacturing company in Hot Springs, Ark. "It's a highly stressful job. You're the middleman, and everybody screams at you," she says. She also concedes that she was driven. "I felt I had to work harder than any





**ADJUSTMENTS.** **The treadmill at the National Park Medical Center's cardio rehab center was the first place Speers felt comfortable "risking" an exercise program. Now she walks 20 minutes a day, usually outdoors with her daughter. Her cardiologist, Michael Frais (below), has been treating her since her heart attack in 2000. Most days, Speers needs several naps—a routine she wouldn't have predicted four years ago. "My life is very sheltered, very quiet." Her dog, Chili, undoubtedly likes the role of companion in her new lifestyle.**

of my peers," she says. "If they got there at 5 [a.m.], I'd get there at 4:30."

She had a family and tackled that job with as much competitive gusto as she gave her day job. "Now I know that the men I worked with would get home and sit in a recliner. I went home to two teenagers and a husband," she says.

To relax during the day, she would smoke. She loved stepping outside the building for the peace, solitude, and respite of a cigarette. At 5 feet, 3 inches and 115 pounds, she thought she was too fat. So she skipped meals, drank coffee all day, and grabbed snacks from the vending machine to keep her energy up. To ease the pressure of home life, she'd pick up a pizza or fried chicken for dinner on her way home from work.

She didn't have a clue what her blood pressure or cholesterol level was. And because she was a 40-year-old woman, nobody ever warned her that she was a heart attack waiting to happen. On that hot July morning, she went to work at 4:30, especially tired and dragging. "Some of my employees told me I looked awful," she says. She paid them no mind. She worked her usual 13-hour day, picked up some supper, ate a few bites and went to bed—exhausted—at 8 p.m. A half hour later, she was pouring sweat as she stumbled to the bathroom and vomited.

She has a fuzzy memory, from the ER, of people whispering about a woman having a heart attack. She looked around to see who the poor little old lady might be. "I had no idea they were talking about *me*," she says. "I had never heard of a woman having a heart attack, much less a 40-year-old woman."

She flat-lined in the emergency room, but the doctors shocked the life back into her. It took at least three jolts. During those minutes, she didn't see a long, black tunnel of the classic near-death experience. It was more like being

on the inside of a tornado.

Speers did a lot of things wrong. She smoked, she ate junk food, she didn't monitor her blood pressure and cholesterol level numbers. She endured high levels of stress for years on end.

And she didn't have the classic heart attack symptoms of pain down the arms, back, neck, jaw, or stomach. Nor the feeling of an elephant sitting on one's chest. But profuse sweating and nausea are also signs. And in women especially, fatigue can be an early warning.

But throughout her massive heart attack, she ignored her body's signals and kept going, giving the myocardial infarction hours to do its damage. She ended up with about two thirds of her heart damaged and a very low "ejection fraction" (the capacity of the heart to pump blood) of 20 percent.

> She had no clue. And because she was a 40-year-old woman, nobody ever warned her that she was a heart attack waiting to happen.

Within months, she had surgery to implant stents to open the blockages in her arteries. The damage done left her too tired to pick up the old lifestyle. "I get up, do a little housework. Then I have to rest," she says.

Now, she's determined to begin doing everything right. She has quit her job, necessary in her case because the extensive damage means she must rest or nap regularly during the day. "My life now is

**MINDFUL.** **Speers (left) and her daughter, Laci, play with cousin Savannah, 2. Breakfast includes orange juice and heart medications. "When you wake up in the morning, you think about your body from head to toe so that when something goes wrong, you recognize it."**

very quiet. I sit back and watch chickens," she says. "If you had told me four years ago I'd be doing that, I wouldn't have believed it."

She doesn't just watch chickens. She is also enrolled in a cardiac rehabilitation program. "When you go to cardiac rehab, you're exercising but you feel safe because you have the monitors," she says. "You learn to feel what's normal and what's not normal."

She follows the recommendations of the American Heart Association for secondary prevention goals for people who have had a heart attack. In addition to her daily walks, she takes an aspirin as well as a beta blocker and an ACE inhibitor to control her blood pressure. She takes a lipid-lowering drug to lower her LDL cholesterol.

She started a healthful diet regimen belatedly. That's because immediately after her heart attack, she read statistics on the odds of dying within months for someone who had suffered the extensive damage that she had. "I felt like I was on death row. I started eating anything that tasted good because I thought it could be my last meal," she said. "And I thought, 'If this is my last meal, I'll be darned if its going to be lettuce. I'm going to eat a big old burrito.'"

After her weight went up by about 30 pounds, and she not only didn't die but kept a slow, steady pace of improvement, she decided to cut out fried foods, salt, and sweets, and to add a lot of fruits and vegetables to her diet. She's determined to get the weight off.

Still, she feels guilty over causing her family anguish. "My husband can't sleep well at night because he's afraid he'll roll over and I'll be dead. I'm such a family person. I try to protect them too much. No one ever told me this, but I'm finding out a lot of women go to a psychiatrist after a heart attack. Maybe that's something I need to pursue."

The experience has caused one other problem, not covered by AHA guidelines. She has insomnia and takes a nightly sleeping pill: "A lot of people who have gone through a traumatic heart experience have trouble sleeping at night. If I didn't take a pill, I'd lay there and listen to my heart beat." ●

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# EYEING SIGNS OF TROUBLE

## Heart disease usually announces itself in unmistakable ways

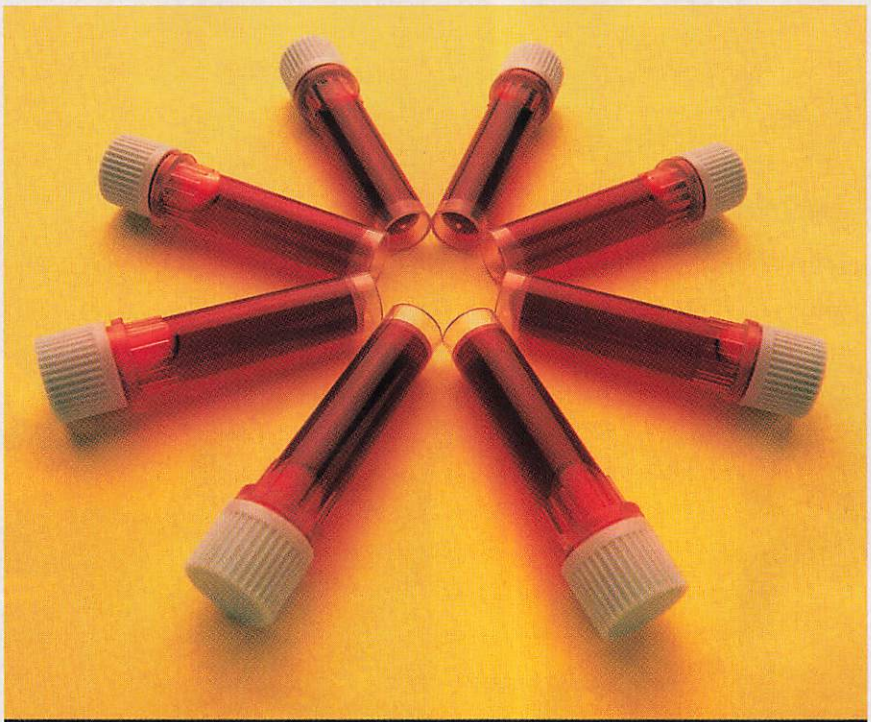
BY AMANDA SPAKE

It was about 10 o'clock on the Saturday night after Thanksgiving when Ann Stiegler had the first fleeting notion that her heart might be in trouble. "I sat down in my chair to watch the late news on television, and all of a sudden I felt pressure in the center of my chest. Then, it sort of went into my neck, and I had tingling down both arms. I remember thinking to myself, 'You know, this seems kind of like a heart attack.'"

Stiegler of Laurel, Md., had been diagnosed with Type II diabetes four years earlier. That's a major coronary risk factor. She was also overweight, had elevated cholesterol, and had a family history of heart disease—all factors that multiplied her chances of suffering a coronary event. But for her part, Stiegler believed she was in good health. At 50, she was 15 years younger than the typical female heart attack victim. She was walking 3 miles a day, had normal blood pressure, and didn't smoke. So that night she took the greatest risk of her life: She went to bed and postponed calling her doctor. "I just didn't think I could be having a heart attack."

**The first hour.** Many people don't recognize the signs of a heart attack or understand the role that lifestyle and medical histories play in increasing their risks. As a result, they don't seek medical care fast enough when their hearts act up. Each year about 1.1 million Americans suffer a heart attack. Half die, and half of those die within the first hour. If those people received medical care in the first hour after the onset of symptoms, fewer than 2 percent of them would die.

The fact is that about one quarter of heart attack victims never even get to a hospital. They die without treatment. Why? "Because the average person delays two to three hours in seeking medical care—even when they have recognizable symptoms of a heart attack," says Joseph Ornato, professor and chairman of the Department of Emergency Medicine at Virginia Commonwealth University Medical Center.



**TELLTALE.** Had a heart attack? The message is in the blood.

Few people have what Ornato calls "the Hollywood heart attack," where they suffer stabbing chest pain and drop to the floor. "That's most likely a sudden cardiac death caused by ventricular fibrillation," a lethal arrhythmia in the lower chambers of the heart that often occurs at the time of or just after a heart attack. About half of people have the typical signs of a heart attack—pressure or squeezing in the chest, pains in the arms, burning or heartburn in the stomach or chest, shortness of breath. "About a quarter of heart attacks are what we call 'silent,'" he says, that is, people have no symptoms and don't know they've had a heart attack. And about one quarter have atypical symptoms—face or jaw pain, fatigue, or nausea.

This is particularly true for women. "Women often feel sick all over, have upper-abdominal or lower-chest pain, nausea, and so the diagnosis may be missed," says Nisha Chandra-Strobos, the coronary care unit director at Johns Hopkins Bayview Medical Center. A recent study of more than 500 women who had heart attacks showed that 95 percent experienced some warning signs a month before their attack. One of the most common warnings signs, ignored by many, doctors say, is unusual fatigue. About 43 percent of the women had no chest discomfort at all. Lack of chest pain, says Jean McSweeney, the lead author of the study, may be a major reason that women's heart attacks are more often unrecognized than men's and that female patients are mistakenly discharged from emergency rooms. "Women are also apt to downplay their symptoms," says Bayview's Chandra-Strobos. "Men are more likely to go to the emergency room with chest pain, and women are more likely to say, 'the repair man is coming' or 'I've got to get

There are about **700,000** strokes a year in the United States—an average of **one** every **45** seconds.



PHOTOGRAPHY BY NICHOLAS EVELEIGH—FOR *USN&WR*

the kids off to school, so I'll take some Maalox and maybe it will go away.' "

**"Biomarkers."** Ann Stiegler not only waited 12 hours to talk to her doctor, she added transportation time by not calling for paramedics and an ambulance to transport her to the hospital. Instead, she relied on her husband to drive. In an ambulance, paramedics begin heart attack treatment, says Virginia Commonwealth's Ornato. They give oxygen and aspirin, they have defibrillators to prevent the patient from dying of a fatal arrhythmia, they go to the correct hospital—one with a coronary care unit and a catheterization lab. It should also come as no surprise that patients who arrive by ambulance are usually seen first. "But the public uses paramedics when they have heart attack symptoms," Ornato laments, "only about 1 in 4 times."

The Rapid Early Action for Coronary Treatment Trial, sponsored by the National Heart, Lung, and Blood Institute, was an 18-month, $20 million media and education effort to reduce the time between heart attack symptoms and care. It was an utter failure. "The bottom line was there was no decrease in the time delay even where there was the massive public education effort," says Ornato. Surveys in the 20 REACT communities showed only a slight increase in residents' knowledge of heart attack symptoms. Ambulance use increased from 33 percent to about 40 percent, but the average time between symptoms and treatment remained about two hours and 20 minutes.

When Stiegler arrived at the emergency room, her first test was an electrocardiogram, a graphic record of electrical activity in her heart. The results indicated normal heart activity. The EKG is supposed to reveal abnormal heartbeats and inadequate blood flow or heart enlargement. But the test provides an immediate diagnosis of a heart attack in a surprisingly small number of cases, only about 10 percent. Blood tests to identify "biomarkers"—enzymes or proteins that appear in blood when a patient has had a heart attack—may not confirm a diagnosis for 12 to 24 hours. The test for the protein troponin is considered the most accurate.

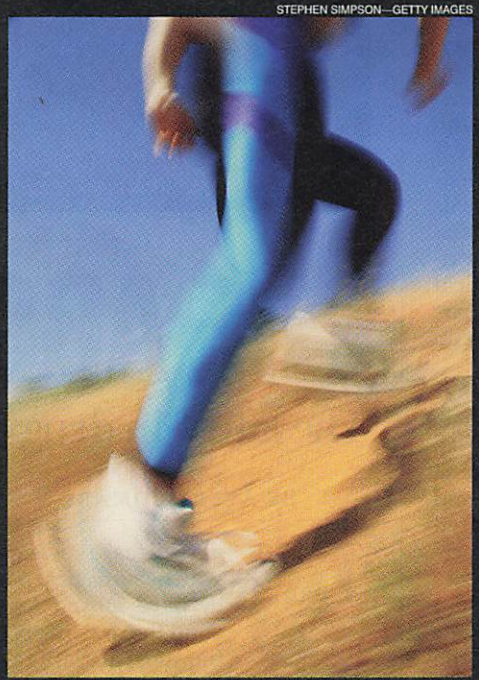
When Stiegler's blood tests were uncertain, doctors scheduled her for an exercise stress test the next day. An exercise stress test, administered on a treadmill or stationary bicycle, shows how well the heart pumps by recording EKG rate and blood pressure at higher

## STOPPING IT BEFORE IT STARTS

For 13 years Joanne Harrell has been studying North Carolina schoolchildren. And like many in the medical community, she has come to believe that the key to preventing heart disease is to modify the eating and exercise habits of children and adolescents before they become new heart statistics as adults.

For more than half a century it's been known that atherosclerosis begins in childhood. What's become clear over the past two decades is that this process can be slowed, even halted, by reducing heart disease risk factors—smoking, hypertension, high LDL cholesterol, insulin resistance, or diabetes—through changes in habits, exercise, and diet.

STEPHEN SIMPSON—GETTY IMAGES



**WORKOUT.** Consider it a heart disease vaccine.

Harrell's Cardiovascular Health in Children and Youth study, for example, demonstrated that school-based intervention can improve fitness and reduce children's heart risks. But recently, Harrell's research revealed a frightening fact: One in eight of the 3,203 North Carolina kids in her study already have three or more of the risk factors for "metabolic syndrome," a serious condition that, in adults, doubles the risk of dying of heart disease. More than half of the kids Harrell is following had at least one risk factor associated with the metabolic syndrome—hypertension, obesity, high triglycerides, low-HDL cholesterol, or high glucose levels. And 13.5 percent had three. Harrell attributes the high level of metabolic syndrome to obesity.

**Lethal tummies.** Lewis Kuller, an epidemiologist at the University of Pittsburgh, agrees. He has been studying metabolic syndrome in a group of 500 women. "It's that abdominal fat that we've discovered that leads to the changes in the body that result in heart disease later," Kuller says. Abdominal fat seems to change the way energy is metabolized, leading to insulin resistance, and an increase in fats in the blood, including LDL cholesterol.

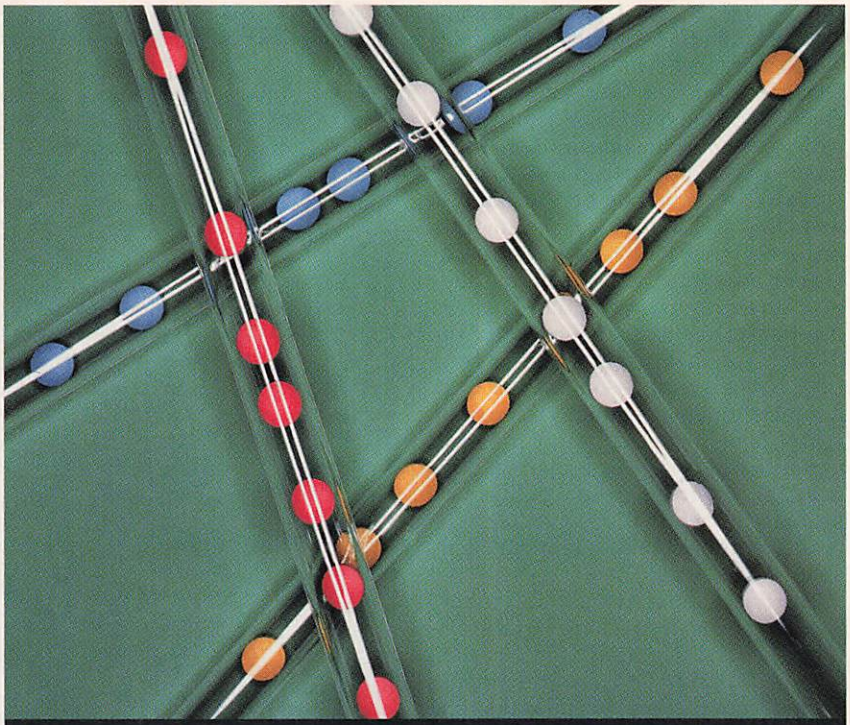
What's the healthiest way to reduce waistlines? Walter Willett, professor of epidemiology and nutrition at the Harvard School of Public Health, has spent a career answering that question: "Replace unhealthy fats—saturated fats in red meat and dairy products, and trans fats from partially hydrogenated oils, with healthy fats in nuts, seeds, and polyunsaturated vegetable oils." Polyunsaturated fats reduce bad cholesterol and can prevent clots from forming in the arteries. "And eat fish twice a week or more." A recent study showed that the omega-3 fatty acids in fish calmed heart arrhythmias and raised good HDL cholesterol. "Also, high fruit and vegetable intake is essential," Willett adds. "With this type of diet, combined with not smoking and regular exercise, we could prevent over 80 percent of the heart disease in the nation—and that's way more than any available drug can do." *–A.S.*

and higher workloads as the patient walks or pedals. But by the next morning, she says, "The doctor came in and said my enzymes showed I'd had a heart attack." After an echocardiogram—an ultrasound image which shows the heart's ability to fill with blood and pump to the rest of the body—Stiegler was transferred to a specialty hospital for angioplasty.

**A look inside.** Angioplasty is done in a cardiac catheterization lab. A thin catheter is threaded through an artery in the groin to the heart. A tiny balloon on the end is inflated to push open the arterial blockage, and sometimes a stent, or wire mesh tube, is inserted in the artery to keep it open. In Stiegler's case, she had three blocked arteries, but they were too small for stents.

When her arteries had closed up again six weeks later, Stiegler was unnerved. After a second angioplasty, Stiegler says, "I fell apart. I was afraid to walk or go anywhere. I kept thinking, 'If it happens again, and I keel over, no one will know who I am or where I came from.'" She started carrying identification on her walks and got a medical alert bracelet that provides the names and numbers of her doctor, husband, son, and her complete medical record with one phone call. "It was part of how I got back to feeling I could do what I wanted again."

It's been nine years now since her heart attack and Stiegler is seriously trying to reduce her heart disease risk factors. "I've totally changed what I eat. I eat no red meat, just chicken and lots of fish. I have dropped saturated fat and cut back on carbohydrates, particularly refined carbohydrates, because they affect my blood sugar and diabetes." She has controlled her LDL, or "bad" cholesterol, with the statin drug called Lipitor. "If you've had a heart attack," she says, "your numbers have to be lower." Indeed, new recommendations on cholesterol indicate those with coronary disease or diabetes need to keep their LDL cholesterol about 40 percent lower than a person without heart disease and no risk factors. She's also taking a beta blocker, a calcium channel blocker, and an ACE inhibitor—all of which reduce the workload and strain on her heart as well as keeping her blood pressure down. She continues to walk, not smoke, and has lost 27 pounds. "I could lose 27 more," she laughs, "but right now, I'm happy to be alive." ●



**HEART PILLS.** Statins work remarkably well, but they're not the only answer.

# THE ARSENAL

## The latest in drugs, surgery, and devices

BY AVERY COMAROW

Heart-disease weapons with near magical potency have moved far beyond the drawing board, but most are still taking their first baby steps. The arsenal already in widespread use by heart doctors, however, is stocked beyond the wildest fantasies of practitioners a decade ago. Better drugs, kinder surgery, and high-tech devices have been coupled with a constantly evolving understanding of how to use them—and on which patients.

**Story of statins.** Start at the pharmacy counter. Long after the 1987 introduction of the first statin (lovastatin, produced by a fungus that can also cause lethal lung infections), many physicians were skeptical. They accepted that statins dramatically lowered LDL—"bad" cholesterol. But they argued that this did not necessarily translate into fewer heart attacks or deaths. Indeed, not until just nine years ago did large studies actually demonstrate that.

Six statins, each more potent than its predecessor, are now on the market. The latest, rosuvastatin, approved in August, was shown in studies to cut LDL by as much as 62 percent in six weeks. One statin, Baycol, was withdrawn from the market in 2001 because of a high incidence of severe muscle weakness and a rash of deaths, but the others have had very few problems. These drugs are being routinely prescribed for people who are not necessarily at high risk for heart problems, to help keep events at bay. And recent studies

**In 2003, cardiovascular disease will cost $210 billion in healthcare and $350 billion in lost productivity.**

# Taking a low-dose aspirin a day for your heart can be a smart thing to do.

# Taking a pain reliever that won't interfere with it is even smarter.

More and more of you are taking a low-dose aspirin for your heart. Smart. But did you know that if you are also taking ibuprofen, the medicine found in Advil, you may not be getting the cardio protection you seek?

Clinical studies have shown that under certain circumstances, frequent use of ibuprofen, like Advil, can actually interfere with your aspirin therapy. It may be blocking your aspirin's ability to thin your blood.

If you are taking a low-dose aspirin a day for your heart, Tylenol may be a better choice. Unlike ibuprofen, Tylenol has not been shown to interfere with your aspirin heart therapy. That's why most doctors recommend Tylenol for people on aspirin therapy. Talk to your doctor about what's right for you.

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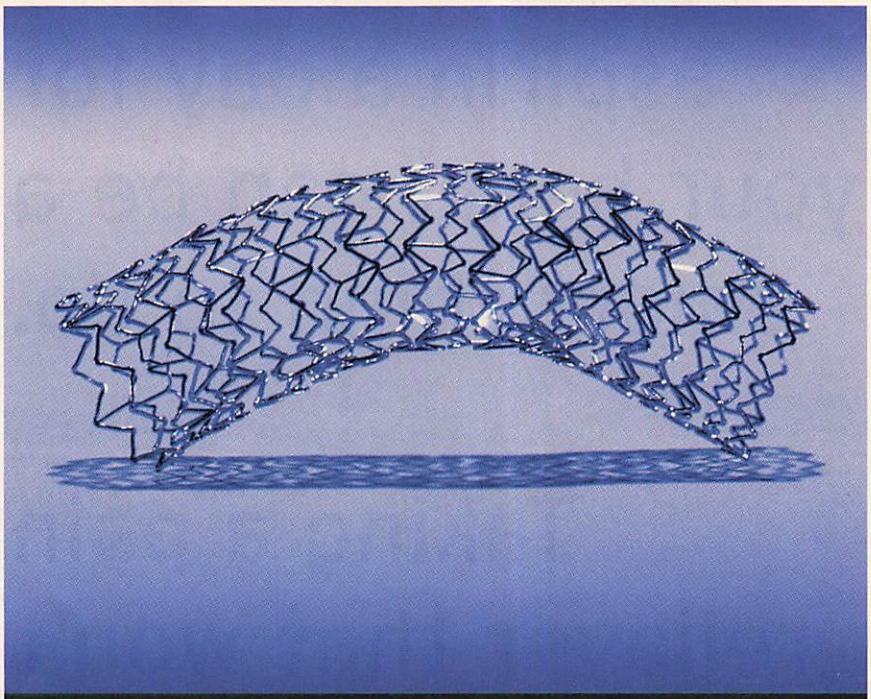
also hint that statins might play a role in preventing stroke and Alzheimer's disease. "We're just starting to understand how powerful the statins are," says University of Michigan cardiologist Kim Eagle.

The nagging question is why more people don't use them. Studies and surveys show that doctors don't prescribe them as often as demonstrated risk would suggest and that when prescribed, the dosages are too low. In addition, patients don't stay on them for long. "To expect the benefits shown in a clinical trial," says cardiologist Christopher Cannon of Brigham and Women's Hospital in Boston, "you have to go with the dose used in the trial."

Most experts believe statin use will increase in the future. It is difficult for them to see why it shouldn't, considering that the majority of men in middle age already have some indication of heart disease.

**The stent option.** Two decades ago, someone with a blocked coronary artery had little alternative but to submit to bypass surgery. That meant days in the hospital, months of uncomfortable recuperation, and a long scar that ached in cold weather as a legacy. Today, cardiologists are giving hundreds of thousands of people every year an option that didn't even appear in the medical statistics 10 years ago: the stent.

Usually an inch or less in length and a fraction of an inch across, this small cylinder of expandable metal mesh holds a coronary artery open after a blockage has been cleared. Inserting it requires only a small cut to gain access to an artery in the groin. The cardiologist passes a long tube—a catheter—into the artery and up toward the heart, monitoring its progress on a TV display.



**STENT.** Fully expanded above, this lifesaving device is about three times actual size.

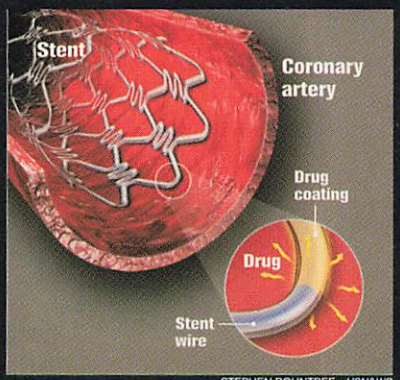
Until a couple of years ago, stenting was always the second step. The first was angioplasty. With that procedure, a small balloon was placed inside the

## KEEPING THINGS CLEAR

The Cypher drug-coated stent was an instant blockbuster. The first such stent on the U.S. market, it was approved by the Food and Drug Administration in April—and by the end of October, Cyphers were propping open blood vessels in some 225,000 Americans. They now account for more than 3 of every 5 stents used, according to Cordis Corp., its manufacturer and a division of Johnson & Johnson.

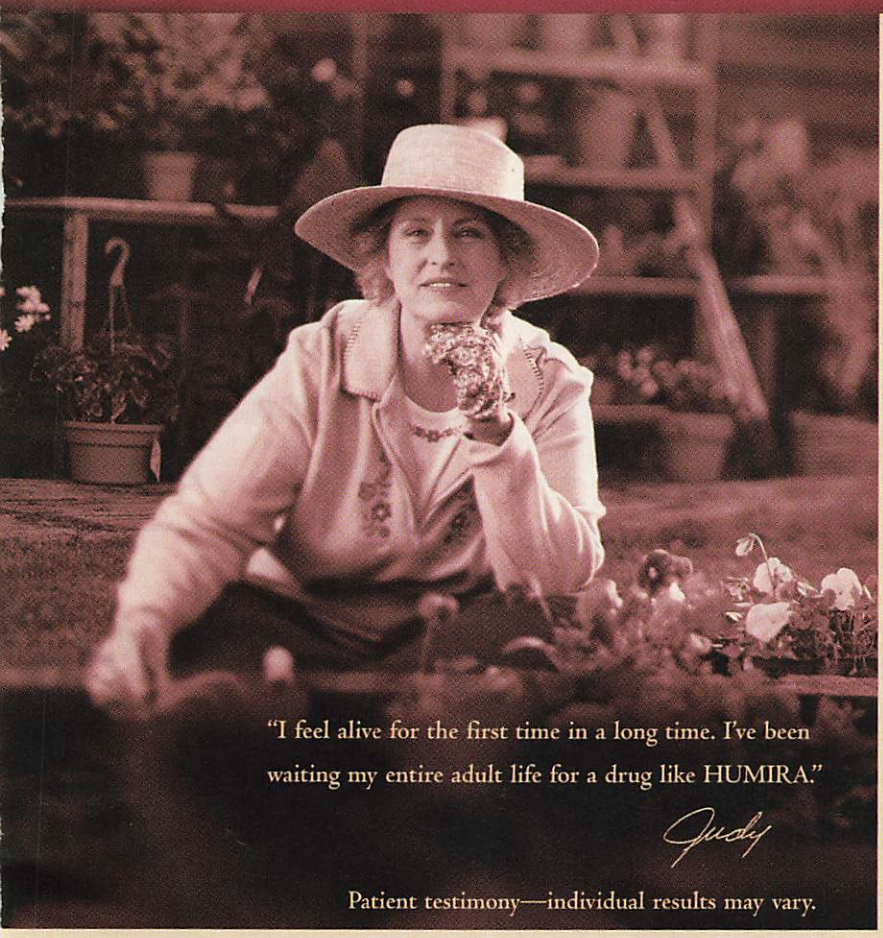
Cordis faces disturbing safety questions about its new product, however. The FDA issued "Dear Doctor" warnings in July and October because of nearly 300 reports of clotting, including more than 60 deaths, and more than 50 possible allergic reactions. Those numbers are a tiny fraction of the Cyphers implanted, but as the first stent of its kind, any reports warrant investigation. Recent Cypher recipients need to take their prescribed antiplatelet medications faithfully to minimize the chance of clotting.

**Nonstick coating.** Older bare-metal stents haven't had these troubles, but they've had a nasty habit of their own. Inserted into newly unblocked coronary arteries to keep the vessels open, uncoated stents can close back up in a few months. The process, called restenosis, occurs from 20 percent to 40 percent of the time. In research studies, the Cypher slashed restenosis rates to well under 10 percent. The key is a thin porous coating containing sirolimus, a transplant antirejection drug that seeps into the artery lining and discourages cell growth.




STEPHEN ROUNTREE—USN&WR

Stents coated with other drugs will soon challenge the Cypher. While coated stents cost several times more than bare ones, many believe they will become the new standard—if the safety issue is resolved. *–A.C.*


"I feel alive for the first time in a long time. I've been waiting my entire adult life for a drug like HUMIRA."
Judy
Patient testimony—individual results may vary.

# Living with rheumatoid arthritis now feels a lot more like normal living.

**HUMIRA: the latest treatment in the fight against rheumatoid arthritis (RA).**

HUMIRA®
(adalimumab)
More Normal Living

Normally, a little gardening wouldn't feel so gratifying. But when you have RA, you know that daily tasks can be overwhelming. Fortunately, that can change. Now there's HUMIRA. It reduces the pain, stiffness, swelling and fatigue of RA. **And more importantly, it helps stop the disease from progressing.**

Clinical studies have shown HUMIRA is safe and works quickly–some people experience relief after just two weeks. And when your RA is under control, you can do more of the daily tasks you'd always taken for granted and enjoy your favorite pastimes.

**RA is a serious disease that can progress quickly. Ask your doctor about HUMIRA today.**
**To receive a free information packet you can discuss with your doctor, call**

**1.800.294.7915**

**w w w . H U M I R A . c o m**

03G-640-9004-1

**What you should know before taking HUMIRA:** HUMIRA is approved for reducing the signs and symptoms and slowing the progression of joint damage in adult patients with moderate to severe RA who have had a poor response to one or more DMARDs (disease-modifying anti-rheumatic drugs). HUMIRA can be used alone or with methotrexate or other DMARDs. Do not start HUMIRA if you are allergic to the drug or any of its ingredients. You should not start HUMIRA if you have an infection, including an infection that is only in one place (such as an open cut or sore) or an infection that is in your whole body (such as the flu). Tell your doctor now if you have a history of recurrent infections or other conditions that increase the risk of infections. **Before starting HUMIRA, your doctor should check you for signs and symptoms of tuberculosis (TB). Tell your doctor if you have ever had TB, or if you have been in close contact with someone who has had TB. Tell your doctor about other medicines that you may be taking. If symptoms of TB (a dry cough that doesn't go away, weight loss, fever, night sweats) or any other infection appear during therapy, tell your doctor immediately.** Tell your doctor if you experience any numbness or tingling, or have or ever had a disease that affects your nervous system like multiple sclerosis, or if you experience allergic reactions such as a severe rash, swollen face or difficulty breathing. Check with your doctor before you receive any vaccines. You should tell your doctor if you are pregnant, become pregnant or are thinking about becoming pregnant. The most common side effects of HUMIRA are upper respiratory and sinus infections, headache, rash, and injection site pain. **Please see adjacent page for product brief summary.**

Abbott Immunology

**BRIEF SUMMARY**

**CONSULT PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION**

# HUMIRA™
## (adalimumab)
## Patient Information

Read this leaflet carefully before you start taking HUMIRA (hu-mare-ah). You should also read this leaflet each time you get your prescription refilled, in case something has changed. The information in this leaflet does not take the place of talking with your doctor before you start taking this medicine and at check ups. Talk to your doctor if you have any questions about your treatment with HUMIRA.

**What is HUMIRA?**
HUMIRA is a medicine that is used in people with moderate to severe rheumatoid arthritis (RA). RA is an inflammatory disease of the joints. People with RA are usually given other medicines for their disease before they are given HUMIRA. HUMIRA is for people with RA who have not responded well enough to these other medicines.

**How does HUMIRA work?**
HUMIRA is a medicine called a *TNF blocker*, that is a type of protein that blocks the action of a substance your body makes called TNF-alpha. TNF-alpha (tumor necrosis factor alpha) is made by your body's immune system. People with RA have too much of it in their bodies..The extra TNF-alpha in your body can attack normal healthy body tissues and cause inflammation especially in the tissues in your bones, cartilage, and joints. HUMIRA helps reduce the signs and symptoms of RA (such as pain and swollen joints) and may help prevent further damage to your bones and joints.

HUMIRA can block the damage that too much TNF-alpha can cause, and it can also lower your body's ability to fight infections. Taking HUMIRA can make you more prone to getting infections or make any infection you have worse.

**Who should not take HUMIRA?**
You should not take HUMIRA if you have an allergy to any of the ingredients in HUMIRA (sodium phosphate, sodium citrate, citric acid, mannitol, and polysorbate 80). The needle cover on the pre-filled syringe contains dry natural rubber. Tell your doctor if you have any allergies to rubber or latex.

**Before you start taking HUMIRA you should tell your doctor if you have or have had any of the following:**

- Any kind of infection including an infection that is in only one place in your body (such as an open cut or sore), or an infection that is in your whole body (such as the flu). Having an infection could put you at risk for serious side effects from HUMIRA. If you are unsure, please ask your doctor.
- A history of infections that keep coming back or other conditions that might increase your risk of infections.
- If you have ever had tuberculosis (TB), or if you have been in close contact with someone who has had tuberculosis. If you develop any of the symptoms of tuberculosis (a dry cough that doesn't go away, weight loss, fever, night sweats) call your doctor right away. Your doctor will need to examine you for TB and perform a skin test.
- If you experience any numbness or tingling or have or have ever had a disease that affects your nervous system like multiple sclerosis.
- If you are scheduled to have major surgery.
- If you are scheduled to be vaccinated for anything.

*If you are not sure or have any questions about any of this information, ask your doctor.*

**What important information do I need to know about side effects with HUMIRA?**
Any medicine can have side effects. Like all medicines that affect your immune system, HUMIRA can cause serious side effects. The possible serious side effects include:

Serious infections: There have been rare cases where patients taking HUMIRA or other TNF-blocking agents have developed serious infections, including tuberculosis (TB) and infections caused by bacteria or fungi. Some patients have died when the bacteria that cause infections have spread throughout their body (sepsis).

Nervous system diseases: There have been rare cases of disorders that affect the nervous system of people taking HUMIRA or other TNF blockers. Signs that you could be experiencing a problem affecting your nervous system include: numbness or tingling, problems with your vision, weakness in your legs and dizziness.

Malignancies: There have been very rare cases of certain kinds of cancer in patients taking HUMIRA or other TNF blockers. People with more serious RA that have had the disease for a long time may have a higher than average risk of getting a kind of cancer that affects the lymph system, called lymphoma. If you take HUMIRA or other TNF blockers, your risk may increase.

Lupus-like symptoms: Some patients have developed lupus-like symptoms that got better after their treatment was stopped. If you have chest pains that do not go away, shortness of breath, joint pain or a rash on your cheeks or arms that is sensitive to the sun, call your doctor right away. Your doctor may decide to stop your treatment.

Allergic reactions: If you develop a severe rash, swollen face or difficulty breathing while taking HUMIRA, call your doctor right away.

**What are the other more common side effects with HUMIRA?**
Many patients experience a reaction where the injection was given. These reactions are usually mild and include redness, rash, swelling, itching or bruising. Usually, the rash will go away within a few days. If the skin around the area where you injected HUMIRA still hurts or is swollen, try using a towel soaked with cold water on the injection site. If you have pain, redness or swelling around the injection site that doesn't go away within a few days or gets worse, call your doctor right away. Other side effects are upper respiratory infections (sinus infections), headache and nausea.

**Can I take HUMIRA if I am pregnant or breast-feeding?**
HUMIRA has not been studied in pregnant women or nursing mothers, so we don't know what the effects are on pregnant women or nursing babies. You should tell your doctor if you are pregnant, become pregnant or are thinking about becoming pregnant.

**Can I take HUMIRA if I am taking other medicines for my RA or other conditions?**
Yes, you can take other medicines provided your doctor has prescribed them, or has told you it is ok to take them while you are taking HUMIRA. It is important that you tell your doctor about any other medicines you are taking for other conditions (for example, high blood pressure medicine) before you start taking HUMIRA.

You should also tell your doctor about any over-the-counter drugs, herbal medicines and vitamin and mineral supplements you are taking.

**You should not take HUMIRA** with other TNF blockers. If you have questions, ask your doctor.

**How do I take HUMIRA?**
You take HUMIRA by giving yourself an injection under the skin once every other week, or more frequently (every week) if your doctor tells you to. If you accidentally take more HUMIRA than you were told to take, you should call your doctor. Make sure you have been shown how to inject HUMIRA before you do it yourself. You can call your doctor or the HUMIRA Patient Resource Center at 1-800-4HUMIRA (448-6472) if you have any questions about giving yourself an injection. Someone you know can also help you with your injection. Remember to take this medicine just as your doctor has told you and do not miss any doses.

**What should I do if I miss a dose of HUMIRA?**
If you forget to take HUMIRA when you are supposed to, inject the next dose right away. Then, take your next dose when your next scheduled dose is due. This will put you back on schedule.

**Is one time better than another for taking HUMIRA?**
Always follow your doctor's instructions about when and how often to take HUMIRA. To help you remember when to take HUMIRA, you can mark your calendar ahead of time with the stickers provided in the back of the patient information booklet. For other information and ideas you can enroll in a patient support program by calling the HUMIRA Patient Resource Center at 1-800-4HUMIRA (448-6472).

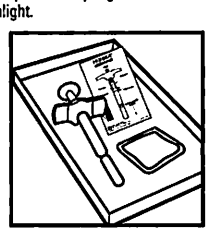
**What do I need to do to prepare and give an injection of HUMIRA?**

**1) Setting up for an injection**

- Find a clean flat working surface.
- Remove one dose tray containing a pre-filled syringe of HUMIRA from the refrigerator. Do not use a pre-filled syringe that is frozen or if it has been left in direct sunlight.

You will need the following items for each dose:

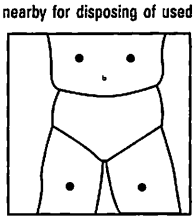
- A dose tray containing a pre-filled syringe of HUMIRA with a fixed needle
- 1 alcohol prep
- The card with the drawing of the pre-filled syringe



If you do not have all of the pieces you need to give yourself an injection, call your pharmacist. Use only the items provided in the box your HUMIRA comes in.

- Check and make sure the name HUMIRA appears on the dose tray and pre-filled syringe label.
- Check the expiration date on the dose tray label and pre-filled syringe to make sure the date has not passed. Do not use a pre-filled syringe if the date has passed.
- Make sure the liquid in the pre-filled syringe is clear and colorless. Do not use a pre-filled syringe if the liquid is cloudy or discolored or has flakes or particles in it.
- Have a puncture proof container nearby for disposing of used needles and syringes.

FOR YOUR PROTECTION, IT IS IMPORTANT THAT YOU FOLLOW THESE INSTRUCTIONS.



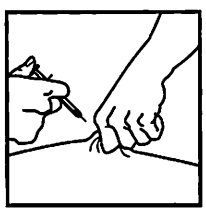
**2) Choosing and preparing an injection site**

- Wash your hands thoroughly
- Choose a site on the front of your thighs or your abdomen. If you choose your abdomen, you should avoid the area 2 inches around your navel.
- Choose a different site each time you give yourself an injection. Each new injection should be given at least one inch from a site you used before. Do **NOT** inject into areas where the skin is tender, bruised, red or hard or where you have scars or stretch marks.
- You may find it helpful to keep notes on the location of previous injections.
- Wipe the site where HUMIRA is to be injected with an alcohol prep, using a circular motion. Do NOT touch this area again until you are ready to inject.

**3) How to prepare your HUMIRA dose for injection with a Pre-filled Syringe**

- Hold the syringe upright with the needle facing down. Take the card with the drawing of the syringe and hold it next to the real syringe so the drawing and the real syringe are side-by-side. Check to make sure that the amount of liquid in the syringe is the same or very close to the 0.8 mL arrow shown on the card with the drawing of the pre-filled syringe. The top of the liquid may be curved as shown in the drawing. The 0.8 mL arrow should point near the middle of the curved liquid. If the real syringe does not have the correct amount of liquid, DO NOT USE THAT SYRINGE. Call your pharmacist.
- Remove the needle cover taking care not to touch the needle with your fingers or allow it to touch any surface.
- Turn the syringe so the needle is facing up and slowly push the plunger in to push the air in the syringe out through the needle. If a small drop of liquid comes out of the needle that is ok.

**4) Injecting HUMIRA**



- With your other hand, gently pinch the cleaned area of skin and hold it firmly. Hold the syringe like a pencil at about a 45° angle to the skin.
- With a quick, short, "dart-like" motion, push the needle into the skin.
- After the needle is in, let go of the skin. Pull back slightly on the plunger, if blood appears in the syringe it means that you have entered a blood vessel. Do not inject HUMIRA. Withdraw the needle and repeat the steps to choose and clean a new injection site. **DO NOT** use the same syringe; discard it in your puncture proof container. If no blood appears, slowly push the plunger all the way in until all of the HUMIRA is injected.
- When the syringe is empty, remove the needle from the skin keeping it at the same angle it was when it was inserted.
- Press a cotton ball over the injection site and hold it for 10 seconds. Do **NOT** rub the injection site. If you have slight bleeding, do not be alarmed.
- Dispose of the syringe immediately.

**5) Disposing of syringes and needles**
You should always check with your healthcare provider for instructions on how to properly dispose of used needles and syringes. You should follow any special state or local laws regarding the proper disposal of needles and syringes. **DO NOT throw the needle or syringe in the household trash or recycle.**

- Place the used needles and syringes in a container made specially for disposing of used syringes and needles (called a "Sharps" container), or a hard plastic container with a screw-on cap or metal container with a plastic lid labeled *"Used Syringes"*. Do not use glass or clear plastic containers.
- Always keep the container out of the reach of children.
- When the container is about two-thirds full, tape the cap or lid down so it does not come off and dispose of it as instructed by your doctor, nurse or pharmacist. DO NOT THROW THE CONTAINER IN THE HOUSEHOLD TRASH OR RECYCLE.
- Used preps may be placed in the trash, unless otherwise instructed by your doctor, nurse or pharmacist. The dose tray and cover may be recycled.

**HOW DO I STORE HUMIRA?**
Store at 2°C – 8°C/36-46°F (in a refrigerator) in the original container until it is used. Protect from light. DO NOT FREEZE HUMIRA. Refrigerated HUMIRA remains stable until the expiration date printed on the pre-filled syringe. If you need to take it with you, such as when traveling, store it in a cool carrier with an ice pack and protect it from light.

Keep HUMIRA, injection supplies, and all other medicines out of the reach of children.

Ref. 03-5236-R2

Revised: January 2003

03E-640-8397-1 **Master**

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North Chicago, IL 60004, U.S.A.

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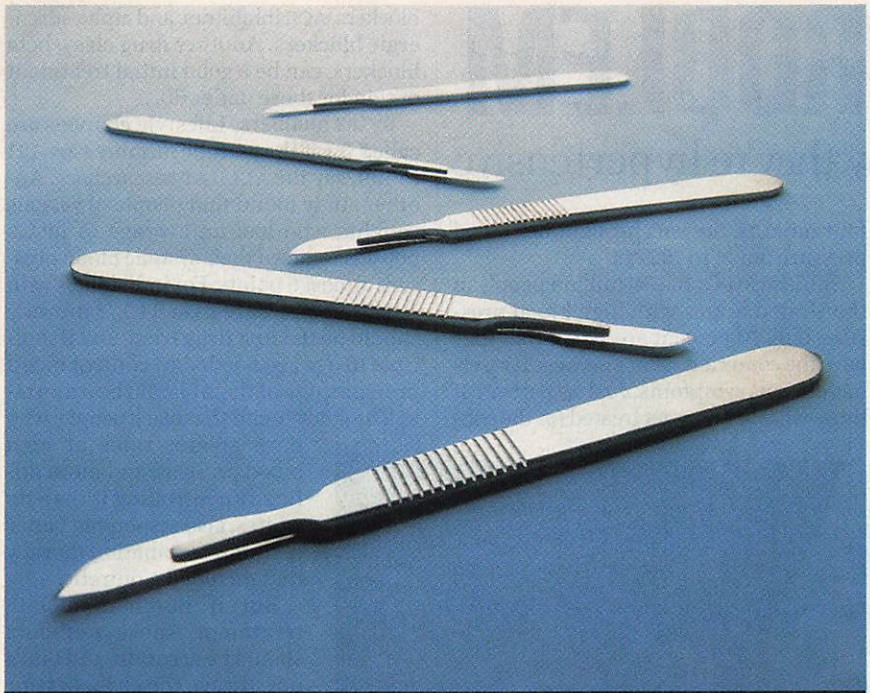


**VANISHING SCALPEL.** Surgery is giving way to procedures done through tubes.

artery and inflated, squashing the blockage against the artery walls. Until the early to mid-'90s, in fact, treatment stopped there. Now POBA (cardiologist humor for "plain old balloon angioplasty") is rare. Indeed, angioplasty is often skipped entirely; the stent is pushed directly into the blocked area and a balloon inside the stent is inflated. The stent expands, locking itself in place; the artery stays open, and surgery has been avoided. Many patients get more than one stent. Some patients go home the same day, and most of the rest leave after an overnight stay.

The downside of stenting is a tendency for the artery to close up again, an apparent reaction by the tissue of the vessel wall to the pressure of the stent. Coating the bare metal with certain drugs may be a workable countermeasure, but the jury is still out (box, Page 58).

**Robots in the OR.** Surgeons are increasingly turning to robotic technology. It's not exactly the way it sounds—the surgeon doesn't sit back and watch while a preprogrammed robot performs an operation. Rather, the surgeon sits at a console and manipulates interchangeable grippers, cutters, and other tools attached to movable arms above the operating table by squeezing and turning hand controls and depressing foot pedals. Looking through two eyepieces, the surgeon gets a 3-D view of the operating field, zooming in and out to achieve the desired perspective.

This works to patients' advantage. Because the video camera and tools can be inserted through 1/2-inch or smaller cuts, large incisions are unnecessary. The implements can turn and bend with more dexterity than the arm and fingers of even a highly dexterous surgeon, permitting tight, foolproof sutures. And the ability to move the small camera lens inside the heart and magnify the field of view permits the surgeon to double-check every aspect of the repair. (A small Catch-22: Robotic procedures take as long or longer than the usual kind partly because of interruptions due to blood splashed on the lens, which has to be withdrawn and washed off.) Even after undergoing delicate work inside the heart, patients often check out of the hospital after a day. Last month a study found that robotically assisted bypass surgery was as effective and safe as conventional surgery. Robotic surgery also has been used in many mitral valve repairs and other heart procedures.

**Surgeons performed 2,202 heart transplant operations in the United States in 2001.**

**Keeping pace.** Many candidates for a heart attack have an abnormal heart rhythm. Others are suffering from heart failure, the inability of the heart to pump sufficiently hard. In either case, they have little incentive to be optimistic. Most people who have a heart attack don't survive unless they are already in the hospital, and medications meant to keep the heart beating smoothly have very mixed results. But the latest implantable cardioverter-defibrillators (ICDs) could save many of these people.

To the average eye, an ICD looks like a slightly bulkier pacemaker—about the size of a pager rather than a matchbook. It is still small enough to be surgically tucked just beneath the skin of the chest. The larger size is because most of today's ICDs are two devices in one. They combine the function of a pacemaker, which senses an abnormally slow heartbeat and generates the missing beats to get the heart back on pace, and a cardioverter, which senses an abnormally rapid heart rate and sends the heart a sharp jolt of electricity to slow it down. (The "defibrillator" function sends an even stronger shock if the heart rhythm becomes erratic.) Even the smaller shocks are uncomfortable for most patients; a defibrillator pulse has been described as the kick of a mule.

But ICDs work. In a recent study, more than 1,200 people with a history of coronary artery disease, a prior heart attack, and existing heart failure were randomly divided into a group that received medical therapy or ICDs. After almost two years, the ICD group had nearly 30 percent fewer deaths. And the newest ICDs send pacing pulses to the left and right ventricles, the heart's major pumps. "Biventricular pacing" is particularly helpful in those in the later stages of advanced heart failure and whose ventricles aren't in sync.

The major issue is cost. It's $15,000 to $50,000 to implant an ICD, which doesn't include the "running costs" over the years for physician exams, maintenance, and other expenses. A Canadian study suggests that ICDs make the most sense in patients with at least two of three risk factors: 70 years or older, advanced heart failure, and an "ejection fraction"—a measure of pumping ability—of 35 percent or less. As with so many advances in medicine, someone has to confront the bottom line. ●

# HIDDEN PROBLEM

## Many people don't know they're hypertensive

BY SUSAN BRINK

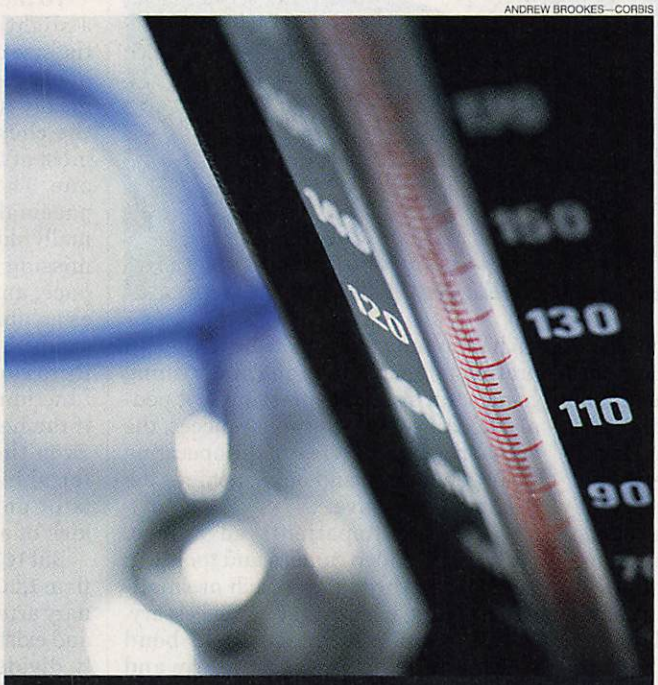
Tangie Stewart tries to walk every day, but exercise, she admits, doesn't come easily. Revamping her diet was a challenge she embraced much more readily; in fact, she made her entire family change with her. "I said, 'This is what we'll be eating. There will be no candy in the house, no salty foods,' " says the 54-year-old resident of Jackson, Miss. She was scared into changing her lifestyle this past July by a blood pressure reading of 150/98.

That put her in the "hypertension" range. In the numbers game of high blood pressure, 120 over 80 is the goal. Anything above those figures can be unhealthy. As the numbers climb, so does the risk of heart attack and stroke, which is what frightened Stewart. Of the two numbers, the first one (the systolic pressure, when the heart contracts to start a heartbeat; the second, or diastolic, is the pressure when the heart relaxes) is more likely to predict trouble. When it reaches 140, doctors start prescribing medication. In some diabetics or people with kidney disease, drug treatment can begin at 130/80.

Stewart's doctor prescribed a diuretic, which reduces the amount of fluid and salt in the body, in addition to diet and exercise. At 5 feet, 7 inches and 150 pounds, Stewart is within a healthy weight range. Still, she went on the DASH (Dietary Approaches to Stop Hypertension) eating plan, because it can reduce systolic blood pressure by 8 to 14 points. When dieters also reduce salt consumption to 2,400 milligrams a day (nearly 30 percent below what Americans typically consume), the pressure number drops an additional 2 to 8 points. In just four months, Stewart brought her blood pressure down to 122/78.

She's lucky. Of the 50 million people in the United States with high blood pressure, only 70 percent are aware that they have the condition. That's because it rarely has obvious symptoms. Just 59 percent of those who do know get treated for the condition, and only 34 percent are able to lower their numbers below 140/90.

ANDREW BROOKES—CORBIS




**UNDER PRESSURE.** Gauges can reveal hidden hypertension.

Diuretics are the oldest, least expensive drugs available in the antihypertension arsenal. And, according to a recent study, they are the best starting point for lowering blood pressure when a drug is needed. The Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT) followed more than 40,000 men and women 55 and older for eight years. The study found that diuretics lowered blood pressure as well as or better than newer, more expensive drugs called calcium channel blockers, ACE inhibitors, and alpha adrenergic blockers. Another drug class, beta blockers, can be a good initial treatment option for those under 60.

**People with less education tend to have higher blood pressure, as do those with lower incomes.**

**By the numbers.** Lifestyle changes are called for if the systolic numbers are 121 to 139, say the ALLHAT researchers. Another study found that people of various weights who lost an average of just 5 pounds reduced their systolic blood pressure almost 6 points. For individuals with a systolic pressure over 140, a diuretic should be the first drug tried, and if multiple drugs are needed to control blood pressure, one of them should be a diuretic. The study found that black people, who have greater rates of high blood pressure and more difficulty controlling it than do whites, also responded better to drug-combination therapy that included a diuretic.

But if numbers dictate treatment, those numbers should be accurate, and that's not always the case. Is your blood pressure the measure the hurried nurse gets after you've been stewing in the waiting room 45 minutes past your appointment time? Or the number the doctor gets when you're half dressed, legs dangling from the examination table? Unnaturally high readings in such situations are common enough to have earned a medical term: the "white coat effect."

There are ways to get better readings. Two measures of blood pressure should be taken and averaged after a patient is seated quietly for at least five minutes in a comfortable chair. And home monitors are becoming increasingly popular. "I think that's probably going to be an important trend for the majority of patients. It makes it relatively easy to see if a drug is working," says Thomas Pickering, who runs the behavioral cardiovascular health and hypertension program at New York's Columbia-Presbyterian Medical Center.

These are strategies that are probably going to become part of the lives of a lot of aging baby boomers as they reach their 50s and 60s. For at 55, even when blood pressure is normal, the lifetime risk of developing hypertension is 90 percent. The boomers, in other words, stand on the threshold of the hypertension years. ●

# reachout

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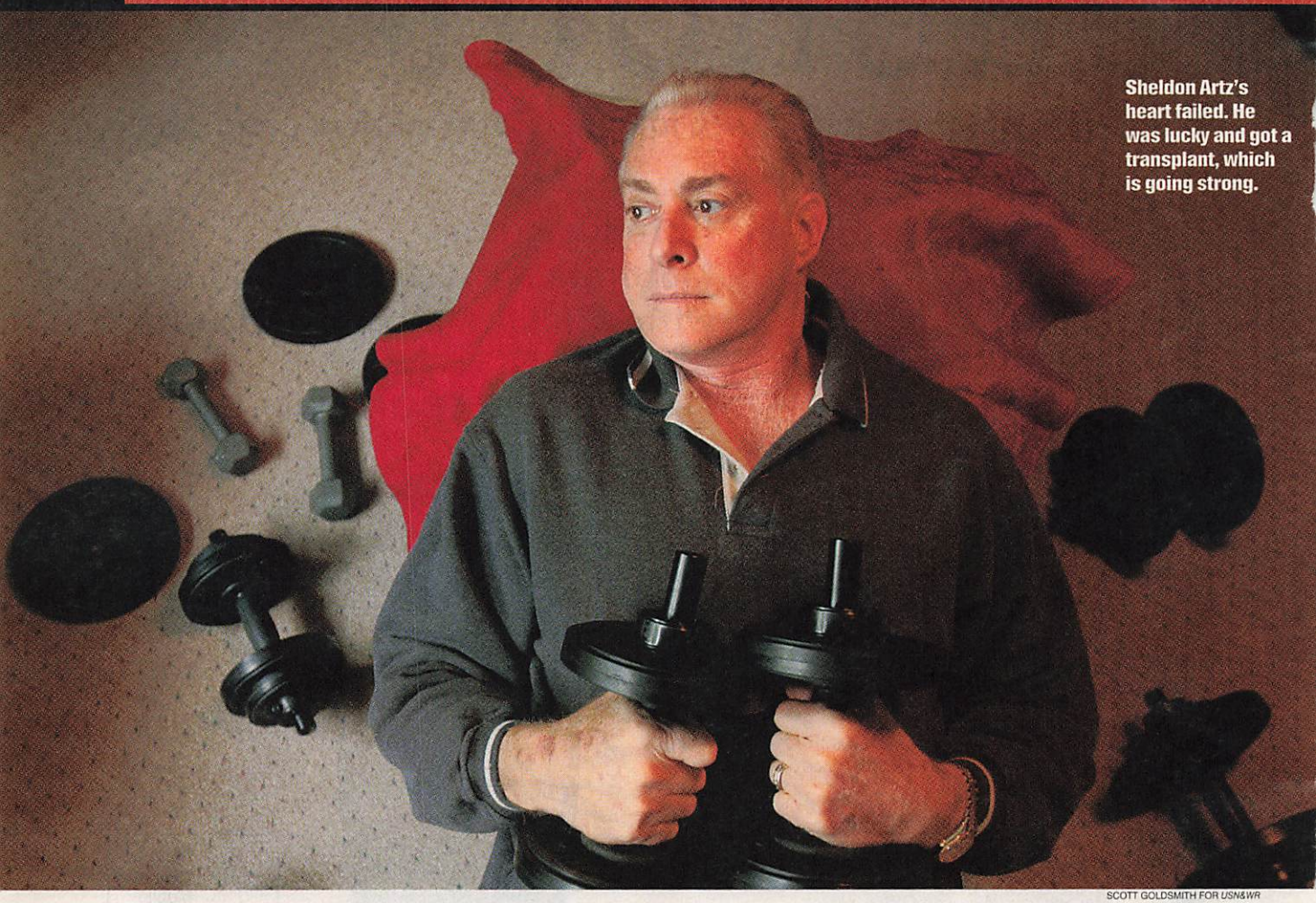


Sheldon Artz's heart failed. He was lucky and got a transplant, which is going strong.

SCOTT GOLDSMITH FOR *USN&WR*

# A REAL FEAR OF FAILURE

## Hearts that struggle to pump are a huge and growing problem

BY KATHERINE HOBSON

Listening to Sheldon Artz's cardiac history is enough to give anyone heart palpitations. In 1991, he felt twinges during a tennis match, ignored them, played a tiebreaker, showered, and then decided to call 911. Artz, now 62, should know better—he's a doctor. Despite the delay, he survived that heart attack and a second one, and then had a triple bypass. The Cleveland-based physician thought he was on the mend. But a few years later he started to experience shortness of breath, muscle weakness, and fatigue. Artz knew what was happening: His heart, injured by the attacks, was having trouble pumping blood throughout his body. Artz had systolic heart failure, the most common form of the disease, and there was no cure.

But there were ways to slow the decay. Artz turned first to a series of drugs that temporarily improved blood-pumping ability and later to a then experimental pacemaker. "They really buy time," he says.

Artz's timing was fortunate. Just about five years before he felt his heart failing, doctors had little to offer people like him but a few palliative drugs to relieve discomfort during an inexorable decline. "I felt rather helpless," says Randall Starling, one of Artz's doctors and the head of heart failure and cardiac transplant medicine at the Cleveland Clinic.

That has changed, and just in time. Heart failure is a huge and growing problem, since the population it most often afflicts—patients over 65—is also huge and growing. The condition accounts for more hospitalizations among this age group than any other disease. The increase also comes, ironically, from the success doctors have had in treating other cardiac diseases. "People used to die from their heart attacks, and most of them don't die anymore," says Joseph Rogers, a cardiologist at Barnes-Jewish Hospital in St. Louis. "What people are left with is damaged heart muscle."

Doctors now know that the body produces a host of hormones to compensate for that muscle's reduced pumping capacity by speeding it up and raising blood pressure. But over time, that can actually hurt more than it helps. "The body's own mechanisms to heal the heart are carried too far," says Frank Smart,

medical director of heart failure and transplantation at the Texas Heart Institute in Houston.

The drugs now being prescribed keep those hormones from reaching their targets and so stave off their damaging effects. The first line of defense: a class of drugs called ACE inhibitors, which lower levels of a hormone that causes high blood pressure. In studies, heart patients who took ACE inhibitors alone had a 25 percent lower risk of dying than those who didn't. Drugs called beta blockers, which prevent adrenaline from accelerating the heart rate, can be even more helpful. A 2001 study found that adding a beta blocker to ACE inhibitors and other drugs resulted in 35 percent fewer deaths than in the group not receiving the drug. "It has revolutionized things in the treatment of heart failure," says Starling.

**Potent cocktails.** The pills can pile up. Patients may take drugs to clear the excess water from the body that accumulates because of the heart's inefficient pumping. Add aspirin to prevent clots, digoxin to strengthen the heartbeat, and maybe a statin to reduce cholesterol, and some patients are taking 10 different medications. But the cocktail often works. "The drugs can slow the progression of the disease, prolong survival, and reverse the damage to the heart," says Smart. Some of these drugs are also used in patients with less common and less fatal diastolic heart failure—when the heart can still pump well but doesn't relax enough to completely fill with blood, leaving the overall pumping volume still reduced.

But medications are not a permanent solution for everyone. That's where some of the newer devices come in—either as temporary help while hoping for a heart transplant or as a longer-term solution. Because saggy, baggy heart muscle doesn't beat smoothly, in 2001 the Food and Drug Administration approved a biventricular pacemaker that places an additional electronic regulator on a wall of the left ventricle to stimulate a more efficient heartbeat. "We've now inactivated a significant number of patients from the heart transplant list because they've done so well," says Gilbert Mudge, director of cardiac transplants at Brigham and Women's Hospital in Boston. Implanted defibrillators may also be used for patients who have heart failure after a heart attack.

More recently, left ventricle assist devices (LVADs)—small, surgically implanted pumps that take over for part of the heart—have become an option. They're approved for patients awaiting transplant. Last year, the FDA approved one, made by Thoratec, a medical device company based in Pleasanton, Calif., as a longer-term solution for seriously ill people who aren't eligible for a transplant. James Dorsey of Westboro, Mass., got one at the end of this past summer. "It's done wonders for me," he says. "I'm back walking a mile a day."

The LVADs aren't perfect. Patients must tote around battery packs—Dorsey uses a fisherman's vest—and some complain about noise and discomfort. The consequences of malfunction are also significant. "When your car won't start, you have a bad day, but when your LVAD doesn't start, you have a *really* bad day," Smart says. Still, there's reason to hope. Because technology is improving and doctors are learning how to avoid complications like infection, Mudge predicts that in five years there will be five to 10 times as many LVAD implants each year as heart transplants—or more than 20,000 a year.

A heart transplant is still often the only solution for end-stage heart failure. They're extremely rare—just about 2,200 are done annually—and are getting more so as demand increases while the supply doesn't.

The inadequacy of the transplant solution has made heart failure treatment a hotbed of research. More drugs may be on the horizon. Researchers now suspect that in addition to the hormones blocked by existing drugs, chemicals released during the body's healing process—inflammation—hurt heart muscle. Vasogen, a Canadian drug company, is now enrolling patients in a large trial to see if its anti-inflammation drug, Celacade, reduces death and hospitalization among heart failure patients.

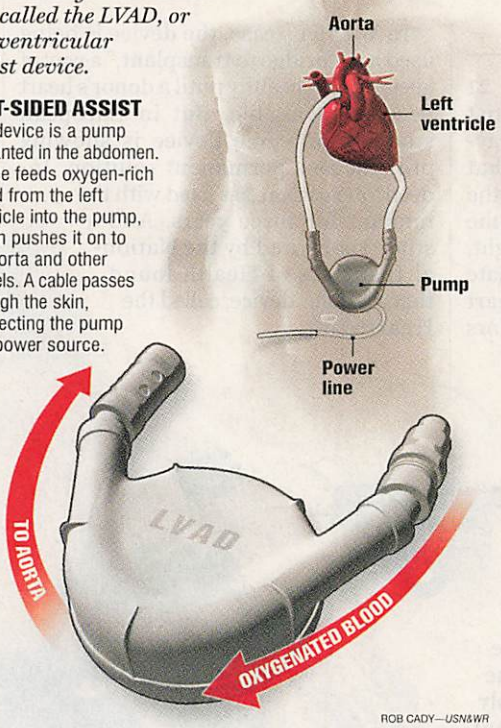
On the device front, the Cleveland Clinic's Starling is studying whether a fabric sheath placed around the heart will prevent it from getting too big and allow better pumping, similar to the way a weightlifter's belt restricts and reinforces stomach muscles. Researchers are also eyeing stem cells, those rare and seemingly magical cells that can mature into any type of organ. At the recent American Heart Association meeting, German researchers said heart attack survivors whose bone marrow stem cells were introduced into the heart appeared to have grown new heart tissue, and saw improvement.

It will likely be years before there is widespread use of stem cells. Artz, using current treatments, ran out of time and heart muscle in 2002. He had to turn to a donor heart, but it didn't start beating when placed in his chest. Again, Artz got lucky and quickly got a second transplant. Though he ran into a string of complications, things are looking up. He's taking tennis lessons and looking forward to a ski trip in January. Doctors, for their part, are looking forward to a day when patients don't need to depend on luck but on heart failure treatments that will be permanent solutions. ●

## A LITTLE HELP

*When a heart fails badly, drugs often don't provide enough help. The chamber called the left ventricle can't pump enough blood back into the body. Enter a new aid called the LVAD, or left ventricular assist device.*

**LEFT-SIDED ASSIST**
The device is a pump implanted in the abdomen. A tube feeds oxygen-rich blood from the left ventricle into the pump, which pushes it on to the aorta and other vessels. A cable passes through the skin, connecting the pump to a power source.




ROB CADY—*USN&WR*

**An estimated 4.8 million Americans have heart failure, and 71 percent of them are age 60 and older.**

# HEARTS OF STEEL

## Two decades since Barney Clark's heroic act

BY JOANNIE FISCHER

On Thanksgiving Day 21 years ago, retired dentist Barney Clark was so ravaged by heart disease that his relatives had to hoist the very tall, very heavy 61-year-old down the stairs so he could say grace. That night, he told his wife that he wanted to donate his life for the cause of artificial heart technology. In early December, doctors implanted a device called the Jarvik-7, and for the next 112 days the world watched in awe as the man-made heart kept the blood coursing through Clark's veins and tethered his soul to his body.

Since that winter of 1982, hundreds of new Barney Clarks have allowed surgeons to cut open their chests and implant various machines in hopes of finding one that can take over when God-given hearts fail. The fantasy of a heart that could be simply swapped in to replace one gone kaput remains fairly elusive, but enormous strides have been made in technology that helps ailing hearts continue to do their job. Thanks to these devices, dozens of people who would have died months or even years ago are out mowing the lawn, watching their kids' soccer games, and—in at least one case—taking up snowboarding.

**Size matters.** After his historic procedure, Clark never left the hospital. The plastic pump in his chest was connected by several tubes to machinery as heavy and large as a refrigerator. Today's pioneers are implanted with devices as small as a C-size battery, connected by one small cord to wearable battery packs. "It's so easy to forget about that sometimes I'll set the pack down and walk away until the yank of the cord reminds me," says David Warner, who is part of a study testing the Jarvik 2000, a pump inserted inside the left ventricle of a weak heart to help draw blood from the lungs and push it forward through the aorta. Warner says it has given him back his life. At age 49, his heart had deteriorated so much that he couldn't walk two blocks. Today he enjoys 2-mile strolls.

In Warner's case, the device is being used as a "bridge to transplant," a way of keeping him healthy until a donor's heart becomes available. But in European studies, the same device is showing promise as a permanent solution. Indeed, one patient has lived with the implant for three years. And a study sponsored by the National Institutes of Health found that a similar device, called the HeartMate, did a better job than standard medical treatments at improving patients' well-being. Last year, the Food and Drug Administration approved its use as a permanent solution, and this year Medicare has agreed to reimburse patients who undergo the procedure.

**SHRINKING.** The state-of-the-art AbioCor heart is completely enclosed inside the body, unlike the massive contraption Barney Clark was hooked up to back in 1982.

Government approval is encouraging the development of ever newer devices. Some of the experimental designs use the same technology as magnetic levitation trains: They allow a tiny suspended rotor to channel blood throught the heart without touching another machine part, avoiding the common wear and tear due to friction. Others aim to get rid of the tube entering the body, which leaves patients vulnerable to infection. One is in the works that would be tiny enough to fit into the heart of a newborn.

But there will always be patients whose hearts are too far gone to benefit from pumping aids, and so the search continues for an actual, self-contained heart that could be transplanted into a patient. The best known "total" replacement heart, called the AbioCor, has been in the works for years. But three of the first five recipients died quickly, dimming enthusiasm for its development. Just last month, a medical group in Japan reported that it had successfully developed a wireless artificial heart. The device had been implanted into cattle, who survived and appeared to be functioning well. One of the selling points of the Japanese heart is that it contains a rechargeable battery that would allow patients to walk around without the clumsy power units. And, because there would be no break in patients' skin, they would be able to shower and bathe normally, something not possible with the current generation of pumps.

It is only a matter of time before total replacement hearts become a reality, says William DeVries, the surgeon who implanted the heart into Clark two decades ago. Meanwhile, these heart-assisting devices give patients a better shot at being around for important anniversaries. "These devices give people enormous hope and peace of mind, knowing that we have options," says Warner, whose oldest child will get married next month. "I can tell you with certainty that for people with serious heart problems, hope is the most essential thing." ●



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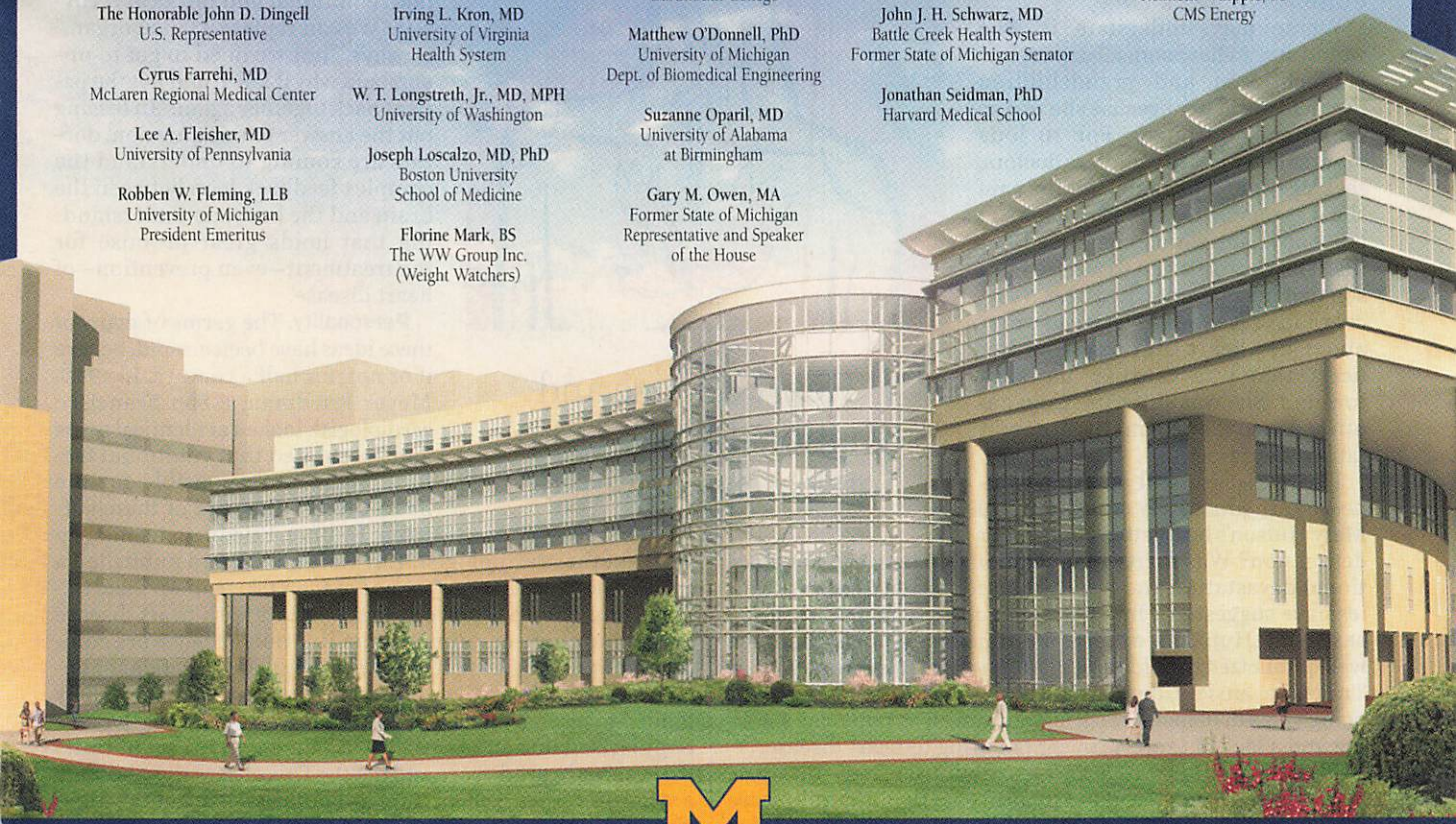

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# HEARTS AND MINDS

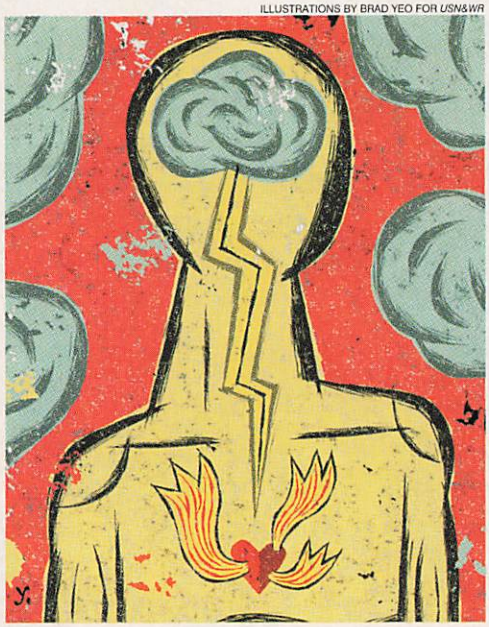
BY MARIANNE SZEGEDY-MASZAK

Nothing prepared Mary Hutson for the emotional hell she inhabited after her second heart attack. Certainly not her first heart attack in 1992. After that one, and the bypass operation that followed, she returned home to her husband and six daughters within a week. At 44, she was sore from the scars but otherwise strong and cheerful about resuming her life as a working mother and active member of Greater Bethlehem Baptist Church in St. Louis.

But when she went to the hospital for a second operation on Feb. 6, 2002, her life was different: She was 10 years older, and five of her kids had left home. Her husband had died several years after their divorce. The hospital experience was much different, too. She experienced three weeks of life-threatening complications. When she finally returned home to her 32-year-old daughter, she completely broke down. "I was fighting something I couldn't see," she recalls. "When the surgery was over, it wasn't the end. It just got worse."

Worse may understate it. She would stay in her room all day crying. Her children and grandchildren began to avoid her because she was so impatient and angry. For 10 long months she went to countless doctors, seeking some explanation for the pain she was unable to locate anywhere in her body, but which consumed her life. The doctors tried to assure Hutson that her operation had been a success and that she didn't have to worry about her heart. But it wasn't her heart that was causing her such torment. She was suffering from another disease, one equally as debilitating: depression.

ILLUSTRATIONS BY BRAD YEO FOR *USN&WR*



"Heart disease and emotional illnesses are intricately entwined."

Heart disease and emotional illnesses are intricately entwined. Did Mary Hutson's heart attack trigger her depression? Was there some relationship between her emotional devastation and her cardiac condition? Lots of studies have suggested a link between depression and heart disease, but Hutson's experience illustrates more than the well-publicized problems of depression after cardiac surgery. Traits like anxiety, depression, and hostility are increasingly being viewed, in fact, as risk factors almost as potent as smoking and a lack of exercise in contributing to heart disease.

It's long been known that acute emotional states—like rage, fear, or panic—can trigger cardiac events that literally "scare you to death." A study published last week in the *Journal of the American College of Cardiology* identified emotional turmoil as a risk factor for both heart attacks and long-term heart health. Controlling for a range of other documented risk factors, the chance of dying following a heart attack was 3.5 times as high in patients like Hutson who suffered from depression. Heart failure patients were more likely to report worsening symptoms, poorer physical function, and a lower quality of life over a six-week period than patients who were not depressed. And that doesn't even factor in the untoward effects of depression on heart-unfriendly behavior: Depressed people tend to smoke more, exercise less, eat bad food, skip their medicine, and live more socially isolated lives.

At the same time, the mind can also serve as a cardiac patient's best friend. The emotional ballast from peer support has proved to be as medically therapeutic as an exercise regimen for cardiac patients. Indeed, cardiac surgeons like Mehmet Oz, the head of the Cardiovascular Institute at Columbia University's Department of Surgery, are now experimenting with subliminal messages to the brain, transmitted on a tape recorder while a patient is on the operating table with his chest pried open, to aid in both emotional and physical recovery. "We can replace a failed organ," Oz says, "but we need to get to understand why it failed and put the patient back together again." In teasing out the answer to this question, doctors are coming to understand the complex feedback loop between the brain and the body, an understanding that holds great promise for the treatment—even prevention—of heart disease.

**Personality.** The germs of many of these ideas have been around, believe it or not, for half a century. In 1943, Meyer Friedman, a San Francisco cardiologist, looked at identical twins and speculated that emotional factors might be responsible for the heart disease that one of them suffered. In 1959, Friedman teamed up with another cardiologist, Ray Rosenman, and published a landmark paper in the *Journal of the American Medical Association*. They pointed out that patients with heart disease seemed to share certain personality traits: They were competitive and achievement oriented; they were impatient or operated with a pervasive sense of urgency; and, finally, they tended to be angry, even hostile. That research led to the now popularized notion of the Type A personality, a set of traits that causes heart disease and death: This observation became a syndrome, then a cliché, and has probably led to more high-powered lawyers' checking their pulses than ever before.

The idea that a particular personality leads inexorably to heart disease has been challenged over time. But most cardiologists and psychologists now accept that certain traits at

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least contribute to the potential for heart problems. As recently as October, researchers reported in the *Journal of the American Medical Association* a strong correlation between impatience and hostility and the long-term risk of developing high blood pressure, a major risk factor for heart disease.

But why? Neuroscientists now understand that intense emotional states create a human stress response gone awry. There are several theories as to what exactly may be happening that makes the stress response exacerbate, even create, cardiac problems. Under stress, the blood-clotting system—especially the sticky cells called platelets—goes on high alert; it's the body's way of slowing down bleeding should there be a wound. However, this same lifesaving clotting in the arteries can also cause heart attacks and strokes. One study found that depressed patients exhibited increased platelet activation in comparison with normal subjects. Stress and anxiety also activate cytokines, chemical messengers from the immune system, which are a known trigger for inflammation in the heart. Recent studies in New York revealed a 35 percent increase in heart attacks (and an additional 40 percent increase in other heart irregularities) following 9/11. A New York hospital reported a doubling of heart arrhythmias in the month following the World Trade Center attacks.

And it doesn't take 9/11-level stress to upset the ticker. Other researchers have examined the way that a normal heart moves between its resting and its beating states. They found that depressed, anxious, and chronically angry people had more-rigid hearts—hearts less able to respond to the changing demands for blood and oxygen. Likewise, hostility and depression are associated with increased activation in the sympathetic nervous system and in the suppression of the parasympathetic nervous system. In other words, the body's natural ability to maintain a balanced state is turned upside down when confronted with long periods of stress, anger, or depression. And when a traumatic event, or intense rage, floods the system with neurochemicals, this, too, can cause a heart attack or the onset of congestive heart failure. Some doctors are even looking at a fundamental paradox: Could the trauma of a cardiac disease diagnosis, or a heart attack, or a heart operation, trigger the very neurochemicals that worsen the problem?

The mind can also serve as a cardiac patient's best friend.

Clinicians have long observed that patients are frequently depressed after a heart attack. Almost 1 in 4 suffers full-blown depression, and an additional 15 percent to 25 percent have some depressive symptoms. Doctors also now know that when patients are depressed and have a heart attack or congestive heart failure, they tend to fare poorly compared with people who are not depressed. They are more likely to have another heart attack and even die. Cardiac surgeons even refer to patients who are depressed after being put on the heart-lung machine as "pump heads." Indeed, depression can be as subtle as a heartbeat, or as obvious as a heart attack.

Many of these depressions resolve themselves after a few weeks. It's the ones that continue for months that can do the most damage. The conundrum, says Nancy Frasure-Smith, a professor of psychiatry at McGill University, is this: "Does depression cause cardiac disease? Does cardiac disease cause depression? Or are they linked by a common factor but there is no causality? And the fact is, it can be all three."

Another puzzle is whether or not treating the depression will, in turn, improve the medical outcomes for cardiac patients. In the largest controlled trial of psychotherapy for cardiac patients ever conducted, ENRICHD (for enhancing recovery in coronary heart disease patients), the answer was disappointing. Patients who were treated for depression improved on some quality-of-life measures but didn't live longer. In this study, 2,481 post-heart-attack patients from 73 hospitals in eight U.S. cities were enrolled in a six-month course of psychological therapy and compared with those who got the usual care. The goal was to find out if this kind of intervention would reduce mortality and the likelihood of another heart attack. While the intervention did reduce depression and social isolation, it didn't affect mortality. And even the quality of life improvements weren't that dramatic. The results were "discouraging," says Robert Carney, a professor of psychiatry at Washington University in St. Louis School of Medicine and one of the principal investigators in the trial. "But we were reminded by cardiologists that there were many unsuccessful cholesterol and antihypertensive studies before they found the right treatment."

While Mary Hutson was not in the ENRICHD trial, she credits this kind of therapy with saving her life. When she thought she could go no lower, she received a call from a woman at the behavioral medicine clinic at Washington University. "Here she was, a total stranger, and I told her that I was suicidal," Hutson says. Hutson participated in a new study organized by Carney. She used no drugs—a relief for Hutson, who was already taking 15 pills a day—but instead joined a support group and became a careful chronicler of her shifts in moods and her fragile dreams and expectations.

Hutson's depression began to lift. Today, she no longer spends her days crying and longing for the end. Her grandchildren now love visiting, and her daughters rejoice that their mother is now her old self. The walk through the shadows of depression is now something Hutson understands. She says emphatically: "I needed someone to say to me, this depression is not because you did something wrong." Now she helps others who turn to her in the depths of their own depression. "I tell them, your body took a big hit. The doctors took out your heart and handled it, and your heart has gotten heavy from being handled." ●

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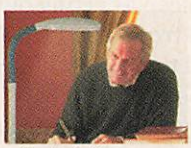

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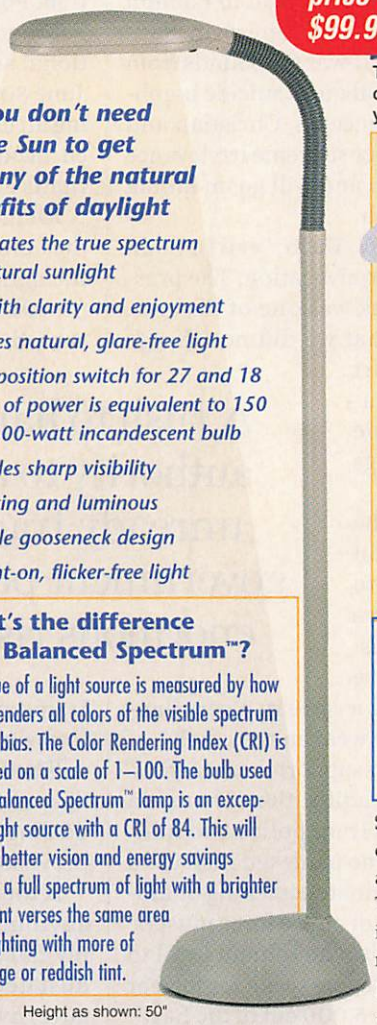

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# Slowly but surely in Iraq

THE ONLY SOUND THAT REALLY MATTERED during the state visit of President Bush to London wasn't the shouting of the anti-American Saddamites in Trafalgar Square. It was the sounds from Istanbul, the agonies inflicted by still more suicide bombings, the senseless slaughter of innocents, Christian and Muslim, right and left—all a matter of supreme irrelevance to the terrorists who kill at random and will go on killing until they are erased from the Earth.

This is, in the words of George W. Bush, "evil in plain sight." About this there can be no equivocation. The president's speech in London last week was one of his best. It was salutary to hear him say that we did not charge hundreds of miles into the heart of Iraq and pay a bitter cost in casualties and liberate 25 million people only to retreat before a band of thugs and assassins.

Does he mean it? Of course. The conviction of the president is not in doubt. There is, however, reason to question the means he seems to have chosen to achieved his desired ends. The new tactics for Iraq's future have been widely perceived as signaling a retreat, a very dangerous perception since it can only weaken the resolve of our friends and encourage those who support the terrorists.

The first perceived retreat was Iraqification. There is a strong argument for putting more Iraqi police and militia on the streets, but there must be no panicked rush to do so. Red flags will be raised if we eliminate screening or dramatically curtail training. A new Iraqi police force must be capable of dealing with those Iraqis who remain loyal to Saddam Hussein. These FRLs (Pentagon-speak for former regime loyalists) may command only 5,000 out of the Baath Party's 1.5 million members. But they have plenty of money and weapons and will not be easy to defeat. Look for them to oppose any Iraqi forces they may face, just as they're challenging U.S. authority there now.

**Election politics.** The second cause for disquiet is the administration's decision to accelerate its timetable for transferring power and sovereignty to an unelected transitional administration. Not long ago, it spoke of three years of constitution writing and institution building, leading—eventually—to elections. Next, it was sovereignty in 18 months. Now, it's June 30, 2004. A process that once was to extend into 2005, well beyond next year's presidential election here, has now been advanced to precede the election. Politics or policy? Here's the latest scenario: By next February, caucuses in Iraq's 18 provinces will choose a national assembly, its members will choose an executive by June 30, and that will be the provisional government pending an election by March 15, 2005. Iraq's Governing Council, meanwhile, will draft new laws enshrining basic human rights and the separation of powers.

All these worthy aspirations may be jeopardized now by the newly accelerated timetable. We have no assurance that the national assembly will emerge from a fair democratic process rather than being hijacked by the ruthless, the corrupt, the better financed. In effect, we may be turning the nascent Iraqi political structure into something like "jump ball"—a far cry from the true balloting of a true democracy.

> A rush to hand authority to an unready Iraqi government poses enormous risk.

This choreography has less to do with the development of democratic institutions in Iraq than with the pressure of democratic politics at home. The administration would like the American public to think, well before the presidential elections, that the Iraqis are taking charge of their own affairs and that our troops are coming home. The perception in the Middle East will be far different: America will be seen as acting out of desperation. If our superbly trained troops had trouble dealing with these terrorists, it's hard to believe the Iraqi provisional government will do any better.

If the endless squabbles on the Governing Council are anything to go by, moreover, the new assembly may simply fall apart, the prospect of elections vanishing like a dust devil in the Iraqi desert. Handing over authority to govern before Iraqis are ready to exercise it would be a tragic miscalculation. It could dash the hopes for a democratic Iraq and a more stable Middle East, while convincing terrorists that if they just keep hitting America long enough and hard enough, we'll lose our will. It could also result in the creation of another failed state that nurtures terrorism, like Lebanon and Afghanistan in the 1980s. The very real possibility is that Iraq would become a haven to terrorists and an even a worse threat than it was under Saddam's misanthropic rule. That would be a disaster for Iraq. But it would also shred America's credibility in the eyes of the world, placing at risk the security of all of us. •

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